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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	20088-13
First Inventor or Application Identifier	Shlomo Ben-Haim
Title	MEDICAL DIAGNOSIS TREATMENT AND ...
Express Mail Label No.	EL007668528

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: **Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231**

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* ____] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* ____]
4. Oath or Declaration [*Total Pages* ____]
   - a. [ ] Newly executed (original or copy)
   - b. [X] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
     - i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   - a. [ ] Computer Readable Copy
   - b. [ ] Paper Copy (identical to computer copy)
   - c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [X] Preliminary Amendment
12. [ ] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [ ] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*

[X] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: 08 / 793,371

Prior application information: *Examiner* B. Casler *Group / Art Unit:* 1911

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

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20088-13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Shlomo Ben-Haim

Serial No.: To be assigned

Filed: Concurrently herewith

For: **MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEM**

March 23, 1999

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

S I R:

Prior to examination, please amend the above-referenced patent application as follows:

IN THE CLAIMS:

Cancel Claims 1 to 68 without prejudice and substitute therefor the following:

-- 69. A system for percutaneous treatment of a patient's heart, comprising:

a catheter, the catheter having a proximal end and a distal end;

an active portion at the distal end of the catheter for applying laser energy operable to ablate a portion of the heart; and

a position sensor operable to provide sensing of the position of the catheter distal end.

-- 70. The system for percutaneous treatment of Claim 69, further including an optical waveguide for energizing the active portion.

-- 71. The system for percutaneous treatment of Claim 70, further including an ECG monitor for synchronizing with the position sensor.

-- 72. The system for percutaneous treatment of Claim 71, further including a reference sensor to correct for breathing motion or patient movement.

-- 73. The system for percutaneous treatment of Claim 69, wherein the position sensor is operable to provide sensing of the position of the catheter distal end by use of magnetic fields.

-- 74. The system for percutaneous treatment of Claim 73, wherein the position sensor includes at least two non-coplanar magnetic elements.

-- 75. The system for percutaneous treatment of Claim 74, further comprising a plurality of external magnetic elements for placement outside the patient.

-- 76. The system for percutaneous treatment of Claim 75, wherein the external magnetic elements establish magnetic fields which are sensed by the position sensor.

-- 77. The system for percutaneous treatment of Claim 76, wherein the plurality of external magnetic elements establish different magnetic fields sequentially and the position sensor is operable to sense the different fields.

-- 78. The system for percutaneous treatment of Claim 77, wherein the plurality of external magnetic elements are three coils, the coils being sequentially energized.

-- 79. The system for percutaneous treatment of Claim 69, wherein the position sensor includes at least one magnetic element and further comprises a plurality of external magnetic elements for placement outside the patient.

-- 80. The system for percutaneous treatment of Claim 70, wherein a chamber of the patient's heart is treated.

-- 81. The system for percutaneous treatment of Claim 74, wherein the position sensor includes wires for carrying position signals between the position sensor and the catheter proximal end.

-- 82. The system for percutaneous treatment of Claim 70, wherein the catheter comprises means for rotating or deflecting the distal end of the catheter.

-- 83. A method of treating a patient' s heart comprising the steps of:

(a) percutaneously inserting a catheter into a heart of a patient, the catheter having a proximal end and a distal end, an

active portion at the distal end of the catheter for applying laser energy, and a position sensor;

(b) sensing the position of the catheter distal end using magnetic fields and the position sensor;

(c) using the position sensor to reference the catheter distal end;

(d) positioning the catheter such that its distal end is adjacent tissue of the heart to be treated; and

(e) applying laser energy from the active portion to the patient's heart tissue.

-- 84. The method of Claim 83, including utilizing an ECG monitor for synchronization with the position sensor.

-- 85. The method of Claim 84, including utilizing a reference sensor to correct for breathing motion or patient movement.

-- 86. The method of Claim 83, wherein laser energy is applied to the active portion through an optical waveguide --.

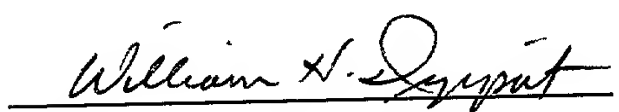
REMARKS

In the amendment above, Claims 1 to 68 have been cancelled in favor of newly added Claims 69 to 115 to more particularly point out and distinctly claim certain aspects of Applicants' invention. At a minimum, support for newly added Claims 69 to 86 can be found, for example, as follows:

Claim	Support
69	Page 15, lines 7-23
70	Page 15, lines 14-16
71	Page 26, lines 3-6
72	Page 26, lines 3-12
73	Page 16, lines 13-15
74	Page 16, lines 13-25
75	Page 17, lines 1-31
76	Page 17, lines 1-31
77	Fig. 1; page 16, lines 13-25; page 17, lines 1-31
78	Page 8, lines 3-5 and 6-10; page 17, line 1, to page 18, line 31
79	Page 15, lines 17-23; page 17, line 1, to page 18, line 31
80	Page 16, lines 28-32
81	Page 18, lines 4-8
82	Page 12, lines 10-34

83	Page 6, lines 31-35; page 7, line 23, to page 8, line 2; page 9,lines 15-20; page 10, line 25, to page 11, line 1; page 15, lines 5-11; page 16, lines 26-36; page 32, lines 19-34; Claims 20, 21, and 33-36
84	Page 26, lines 3-6
85	Page 26, lines 6-9
86	Page 15, lines 14-16; page 18, lines 28-31

Respectfully submitted,



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MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

FIELD OF THE INVENTION

The present invention relates to medical diagnosis, treatment and imaging systems. More particularly, the present invention relates to medical probes whose location can be detected and adjusted and which have an additional detection, imaging and/or treatment function.

BACKGROUND OF THE INVENTION

Probes, such as catheters, suitable for various medical procedures and internal imaging, are fairly common. Such probes include: balloon angioplasty catheters, catheters with laser-, electrical- or cryo-ablation characteristics, catheters having ultrasound imaging heads, probes used for nearly incisionless-surgery or diagnosis, and endoscopes. Where such probes are used for treatment, the probes must be carefully positioned in relation to the body structure. Even for imaging systems such as ultrasound systems, some positioning capability has been described.

In cardiovascular examinations and in particular in those using invasive techniques, multiple catheters are inserted into the vascular system and then advanced towards the cardiac chambers. The procedure itself is generally performed under fluoroscope guidance which necessitates the use of a continuous source of x-ray as a transillumination source. The image generated using the fluoroscope is a 2D display of the anatomy with the location of the catheter superimposed. The anatomy can be viewed with a relatively low resolution since the cardiac chamber and the blood vessels are transparent to the x-ray radiation.

More recently, several technologies have been developed to ease the process of cardiac catheterization, mainly by enabling the physician to follow the path of the tip of the catheter inside the blood vessel. Some of this technology is based on digital subtraction radiography technology that enables viewing the blood vessel after the injection of a radio contrast dye and superimposing on that image the path

of the catheter. These technologies necessitate the use of radiopaque dyes which are a major cause of morbidity in high-risk patients during cardiac catheterization.

U.S. Patent No. 5,042,486 to Pfeiller et al., the disclosure of which is incorporated herein by reference, describes a method in which the position of a catheter tip is located using electromagnetic fields. The catheter is introduced and the tip location is followed. The path of the tip is superimposed on the pre-registered image of the blood vessel or the organ, through which the catheter was advanced. However, this technology requires acquisition and processing of images prior to the procedure and involves a highly sophisticated and time-consuming procedure for the correct alignment of the image acquired previous to this procedure, and the orientation and location of the blood vessel or the organ during the catheterization procedure itself.

U.S. Patent 4,821,731 to Martinelli et al., the disclosure of which is incorporated herein by reference, discloses a method for internal imaging of a living body using ultrasound. In this patent the position of an ultrasound imaging catheter is determined by computing the relative position of the catheter using the response of an ultrasound transducer to a reference signal and by computing the angular orientation of the catheter about its axis by determining the signal induced in a single coil by substantially perpendicular magnetic fields of different frequencies. The ultrasound transducer is also used to send and detect ultrasound signals in a direction perpendicular to the catheter axis. By rotating the catheter and moving it along its axis an ultrasound image may be generated. The catheter is also described as being capable of transmitting a laser beam to the end thereof to ablate tissue from lesions on the walls of arteries.

A catheter which can be located in a patient using an ultrasound transmitter located in the catheter, is disclosed

in U.S. Patent No. 4,697,595 and in the technical note "Ultrasonically Marked Catheter, a Method for Positive Echographic Catheter Position and Identification", Bryer et al., Medical and Biological Engineering and Computing, May, 1985, pages 268-271. Also, U.S. Patent No. 5,042,486 discloses a catheter which can be located in patients using non-ionizing fields and suitably imposing catheter location on a previously obtained radiological image of the blood vessel.

PCT Patent Publication WO 94/0938, the disclosure of which is incorporated herein by reference, describes a system using a single-coil type sensor which is coaxial with the long axis of a catheter and which senses fields which are generated by three multicoil generators external to the body of a patient.

Other methods and apparatus for the determination of the position of a catheter or endoscope are shown in U.S. Patents 5,253,647; 5,057,095; 4,095,698; 5,318,025; 5,271,400; 5,211,165; 5,265,610; 5,255,680; 5,251,635 and 5,265,611.

U.S. Patent No. 3,644,825 describes a system which uses the relative motion of a sensor in the determination of its position. The relative motion supplies information to the sensing coils needed to identify position and orientation. However, such a solution is not applicable to identifying position and location of the object where there is no relative motion between the object and the reference frame.

U.S. Patent No. 3,868,565, the disclosure of which is incorporated herein by reference, comprises a tracking system for continuously determining the relative position and orientation of a remote object. This tracking system includes orthogonally positioned loops for both a plurality of sensors and a plurality of radiating antennas. With the proper excitation currents to those loops, the radiating antennas generate an electromagnetic field that is radiated from those antennas to the sensor. The tracking system

operates as a closed loop system where a controlling means measures the field that is received at the sensor at the remote object and feeds the information back to radiating antennas to provide a nutating field radiating as a pointing vector towards the remote object. Accordingly, the pointing vector gives the direction to the sensing antenna from the radiating antenna.

Similarly, Kuipers describes in his U.S. Patent No. 4,017,858, the disclosure of which is incorporated herein by reference, an electromagnetic field which rotates about a pointing vector and is used both to track or locate the remote object in addition to determining the relative orientation of the object. This system, wherein the radiating coils are charged with the properly designed wave forms, generates a magnetic field which, in a closed loop manner, can be fed into processing means to generate the information needed to determine an orientation of a remote object.

U.S. Patent No. 4,054,881, the disclosure of which is incorporated herein by reference, describes a non-tracking system for determining the position and location of a remote object with respect to a reference frame. This is accomplished by applying electrical signals to each of three mutually-orthogonal, radiating antennas, the electrical signals being multiplexed with respect to each other and containing information characterizing the polarity and magnetic moment of the radiated electromagnetic fields. The radiated fields are detected and measured by the three mutually orthogonal receiving antennas having a known relationship to the remote object, which produce nine parameters. These nine parameters, in combination with one known position or orientation parameter, are sufficient to determine the position and orientation parameters of the receiving antennas with respect to the position and orientation of the radiating antennas.

U.S. Patent No. 4,849,692, the disclosure of which is

incorporated herein by reference, describes a quantitative method for measuring the relative position and orientation of two bodies in the presence of metals. Measuring the position and orientation of receiving antennas with respect to the transmitting antennas is achieved using direct current electromagnetic field signals. Electromagnetic radiation is designed to be transmitted in a sequence by each of the mutually orthogonal radiating antennas. A receiving antenna measures the values of transmitted direct current magnetic fields, one dimension at a time, and those of the earth's magnetic field as well. This method requires repetitive acquisition and computations to determine position and location of remote objects.

Other methods which are known in the art for determining multi-dimensional positioning and orientation for aircraft and for helmets are described in U.S. Patent 4,849,692, European patent publication 0 576 187 A1, GB patent publication 2 197 078 A and U.S. Patent 4,314,251 the disclosures of which are incorporated herein by reference.

The above described prior art which is for use in non-medical applications, utilizes sensors and other structures which are not suitable for use in catheters. Those references which are described as being useful for medical probes generally give less than six dimensional information (three position coordinates and three angular coordinates).

In previous, as yet unpublished applications assigned to the assignee of the present application, U.S. Patent Application Number 08/094,539, filed July 20, 1993 and PCT Application PCT/US94/08352 filed July 20, 1994, the disclosures of which are incorporated herein by reference, a system is disclosed which incorporates a catheter which includes a position measuring device which can determine the position of the catheter in three dimensions, but not its orientation. In these applications, this catheter is used to map the electrical activity at the inner walls of the heart

and to ablate portions of the heart muscle in response to such mappings. The position of the catheter used for the mapping/ablation function is determined with reference to three position detecting devices which are positioned against the inner wall of the heart at three different stable locations to form a reference plane.

SUMMARY OF THE INVENTION

In general the present application discloses a catheter locating means and method that offers quantitative, high resolution locating information that, when assimilated with sensed local information results in a high resolution, detailed map of the information. This map may optionally be superimposed on an image or other representation of the organ architecture.

The locating means preferably generates continuous location and orientation information concerning a remote object, in particular a catheter, relative to a reference frame, in a non-iterative manner.

One aspect of the present invention relates to the provision of a new six-dimensional positioning apparatus suitable for use with a catheter.

In a preferred embodiment of this system, a plurality of non-concentric coils are placed in a catheter adjacent a locatable site, for example, its distal end. The coils preferably have orthogonal axis. The relative positioning of the coils differs from that described in the prior art in that the coils are separated in space and are not concentric. These coils generate signals in response to externally applied magnetic fields which allows for the computation of six position and orientation dimensions.

A second aspect of the present invention is directed toward a new method for computing multi-dimensional position and orientation of a coil system from signals produced by the coils in response to a system of externally applied electromagnetic fields.

A third aspect of the present invention allows for the

mapping of the interior of the heart in a manner similar to that described in the above-referenced patent applications assigned to the assignee of the present application, with the simplification that only a single six-dimensional location/orientation detection sensor is used for reference.

A fourth aspect of the present invention involves an ultrasonic or other imaging probe having a six-dimensional positioning capability in response to external electromagnetic fields. Use of such a probe obviates the use of ionizing radiation or sonic sensing for position determination and gives ultrasonic or other imaging information whose direction and orientation is completely known.

A fifth aspect of the invention involves methods and apparatus for adding a controlled change in orientation to a catheter, thereby to allow for maneuvering of the cathode and its easy placement.

A sixth aspect of the invention utilizes the controlled change in orientation to allow for two or three-dimensional imaging using a non-scanning probe, such as an ultrasound probe or for three-dimensional scanning using a two-dimensional scanning probe.

There is therefore provided, in accordance with a preferred embodiment of the invention, a locating system for determining the location and orientation of an invasive medical instrument, for example a catheter or endoscope, relative to a reference frame, comprising:

a plurality of field generators which generate known, distinguishable fields, preferably continuous AC magnetic fields, in response to drive signals;

a plurality of sensors situated in the invasive medical instrument proximate the distal end thereof which generate sensor signals in response to said fields; and

a signal processor which has an input for a plurality of signals corresponding to said drive signals and said sensor signals and which produces the three location

coordinates and three orientation coordinates of a point on the invasive medical instrument.

Preferably one or both of the plurality of field generators or sensors comprises three distinguishable, non-overlapping, generators or sensors.

In a preferred embodiment of the invention, each sensor comprises a coil. Preferably, said plurality of coils have axes which intersect within a coil. When said plurality of coils comprises three coils, said coils preferably have axes which do not all intersect in a point.

Preferably, the signal processor cross-correlates the signals corresponding to the drive and sensor signals.

Preferably, the fields generated by each of the generators have a different frequency, a different phase, or both a different frequency and a different phase.

In a preferred embodiment of the invention the field generated by each field generator has a different frequency, preferably frequencies which are each integer multiples of a given frequency. Preferably, the duration of the cross-correlation of the inputs is the minimal common product of the integer multipliers divided by the given frequency.

Preferably, the results of the cross-correlation are used to calculate the contribution of each field generator to the signal generated by each said sensor.

In a preferred embodiment of the invention the locating system includes a display system for displaying the position of the point on the invasive medical instrument.

Preferably, the locating system further comprises a reference instrument which includes a plurality of non-overlapping sensors situated in the reference instrument which sensors generate sensor signals in response to said fields, wherein said display system displays the position of the point on the invasive medical instrument relative to the position of a point on the reference instrument. Preferably the reference instrument is an invasive medical instrument. Preferably, the sensors are situated proximate the distal

end of the reference invasive medical instrument.

In a preferred embodiment of the invention the locating system includes an additional sensor on a portion of the invasive medical instrument which senses a local condition.

Preferably, the additional sensor senses local electrical signals, for example electrical signals from the endocardium of the patient's heart, and transfers them to terminals external to the patient's body.

In a preferred embodiment of the invention the signal processor processes the position and orientation coordinate signals and the local electrical signals acquired at a plurality of points on the endocardium to generate a map that represents the propagation of electrical signals through tissue in the patient's body.

In a preferred embodiment of the invention the additional sensor supplies electrical energy to the endocardium for ablating a portion of the endocardium.

Preferably the locating system includes an electrode adapted for supplying electrical energy to the endocardium for ablating a portion of the endocardium.

In a preferred embodiment of the invention the additional sensor is an ultrasonic transmitter/receiver.

Preferably, the ultrasonic transmitter/receiver provides a less than three dimensional representation of the acoustic properties of tissue beyond the distal end.

In a preferred embodiment of the invention, the distal end is deflectable. Preferably, the system includes image reconstruction circuitry which receives a plurality of said less than three dimensional representations acquired at different orientations of the distal end and produces a three dimensional map of the acoustic properties of tissue at least partially surrounding the distal end.

There is further provided, in accordance with a preferred embodiment of the invention, an imaging system for intrabody ultrasonic imaging comprising:

a invasive medical instrument, preferably, a catheter

or endoscope, having an axial-looking ultrasonic imaging transducer at the distal end thereof which generated a representation, preferably a one or two dimensional representation, of the acoustic properties of tissue beyond the distal end;

means for manipulating the distal end to change the orientation thereof; and

image reconstruction circuitry which receives a plurality of said representations acquired at different orientations of the distal end and produces a three dimensional map of the acoustic properties of tissue at least partially surrounding the distal end from said plurality of representations.

Preferably, the imaging system further comprises:

a plurality of field generators which generate known, distinguishable fields in response to drive signals;

a plurality of sensors situated in the invasive medical instrument proximate the distal end thereof which generate sensor signals in response to said fields; and

a signal processor which has an input for a plurality of signals corresponding to said drive signals and said sensor signals and which produces three location coordinates and three orientation coordinates of the a point on the transducer.

There is further provided a method of determining the position and orientation of an invasive medical instrument, for example a catheter or endoscope, having a distal end, comprising:

(a) generating a plurality, preferably three, of distinguishable, geometrically different AC magnetic fields;

(b) sensing the AC magnetic fields at the sensors at a plurality of points proximate the distal end; and

(c) computing six dimensions of position and orientation of a portion of the invasive medical instrument responsive to signals representative of the generated

magnetic fields and the sensed magnetic fields.

Preferably, the AC magnetic field is sensed at three points of the invasive medical instrument.

There is further provided, in accordance with a preferred embodiment of the invention, an ultrasonic intra-body imaging method comprising:

(a) inserting an ultrasonic transducer into the body, said ultrasonic transducer producing a representation of the acoustic properties of tissue beyond an end of the transducer;

(b) manipulating the orientation of the transducer to provide a plurality of said representations; and

(c) constructing a three dimensional map of the acoustic properties of the tissue in a region at least partially surrounding the end of the transducer from said plurality of representations.

Preferably, the method includes determining the six dimensions of position and orientation of the transducer for each of the representations.

Preferably, the representation is a less than three dimensional representation.

There is further provided an invasive medical instrument, for example a catheter or endoscope, comprising a plurality of magnetic field sensors, preferably coils, proximate the distal end thereof.

Preferably the plurality of coils have axes which intersect within a coil. Where the plurality is three, the said coils have axes which do not all intersect in a point.

In a preferred embodiment of the invention, the instrument comprises an ultrasound transducer at said distal end. Preferably, the ultrasound transducer provides a representation, preferably a one or two dimensional representation, of the acoustic properties of tissue beyond and along the axis of the catheter.

In a preferred embodiment of the invention, the instrument further comprises an electrical probe at said

distal end. The probe is preferably adapted to sense electrical signals generated by tissue which is in contact and conduct said signals to the proximal end of the catheter and/or to supply an ablative electrical signal to tissue contacting said terminal. In a preferred embodiment of the invention, the instrument includes a sensor for measuring local chemistry at the distal end.

Preferably, the instrument includes means for changing the orientation of the distal end.

There is further provided, in accordance with a preferred embodiment of the invention, apparatus for steering the distal end of an invasive medical instrument, such as a catheter or endoscope, comprising:

a relatively more flexible wire passing through the catheter that is attached to the distal end and has a bend near the distal end;

a relatively more rigid sleeve which is straight near the distal end and which slideably holds the wire thereat, whereby when the sleeve is slid over the wire, the wire and distal end are straightened.

Preferably, the instrument has a lengthwise axis and the wire is sited off the axis of the instrument.

There is further provided apparatus for steering the distal end of an invasive medical instrument comprising:

a flat relatively flexible portion being slit along a portion of the length thereof to form two portions which are attached at a first end thereof, said first end being attached to the distal end of the instrument;

a pair of wires, one end of each of which being attached to one of said portions at a second end thereof; and

means for changing the relative lengths of the wires whereby the flexible element is bent, thereby steering the distal end of the instrument.

There is further provided, in accordance with a preferred embodiment of the invention, a method of producing

a three dimensional image of the internal surface of an internal body organ comprising:

measuring the distance to said surface at a plurality of orientations from within the internal surface; and

assembling the distances to form an image of the surface.

Preferably, the measurement of distances is made from a plurality of points within the organ. Preferably, the measurement of distances is preformed utilizing an ultrasonic transducer.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a pictorial representation of the application of a system for six-dimensional position and bearing determination, in accordance with a preferred embodiment of the invention to a catheter located in a human body;

Fig. 2 is a schematic, cut-away illustration of a generalized catheter having a six-dimensional location capability in accordance with a preferred embodiment of the present invention;

Fig. 3 is a more graphic illustration of a portion of the probe showing a preferred embodiment of a sensor for six-dimensional location;

Fig. 4 is a block diagram of circuitry used to determine the six-dimensional coordinates of a catheter, in accordance with a preferred embodiment of the invention;

Fig. 5 shows in expanded detail the basic flow chart representing a control sequence and its application to the block diagram of Fig. 4, in accordance with a preferred embodiment of the invention;

Fig. 6 is a block diagram representing digital signal processing in the signal processor in accordance with a preferred embodiment of the invention;

Fig. 7 is a three-dimensional graphic representation of the vectors forming the magnetic field at a point;

Fig. 8 is a block diagram representing analog signal processing in the signal processor, in accordance with a

preferred embodiment of the invention;

Fig. 9 is a simplified schematic of an analog filter element shown in Fig. 8, in accordance with a preferred embodiment of the invention;

Figs. 10A-10D illustrate a principle of orienting the tip of a catheter in accordance with a first preferred embodiment of the invention;

Fig. 11 illustrates a principle of orienting the tip of a catheter in accordance with a second preferred embodiment of the invention;

Fig. 12 is a block diagram of ultrasonic acquisition and signal processing circuitry in accordance with a preferred embodiment of the invention;

Fig. 13 is a block diagram of image reconstruction circuitry in accordance with a preferred embodiment of the invention;

Fig. 14 is a partially schematic, partially cut-away illustration of a probe for electrical sensing, pacing and ablation in accordance with a preferred embodiment of the invention;

Fig. 15 is a schematic block diagram for acquiring a basic electrogram map in accordance with a preferred embodiment of the present invention;

Fig. 16 is a schematic block diagram representing a computerized endocardial mapping algorithm, in accordance with a preferred embodiment of the invention;

Fig. 17 is a schematic block diagram representing a computerized pace mapping algorithm, in accordance with a preferred embodiment of the invention;

Fig. 18 is a schematic block diagram of an algorithm used to calculate the cross-correlation index while pace-mapping, in accordance with a preferred embodiment of the invention; and

Fig. 19 is a schematic block diagram representing an output configuration of an imaging system in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 shows a pictorial representation of a basic preferred application of the invention to the human body. In this application, a catheter 10 is inserted into an artery 11 of a patient using standard techniques. Catheter 10 comprises a body 12, a locating sensor 14 and an active portion 16 at the distal end 15 of the catheter. The active portion 16, in accordance with various preferred embodiments of the invention, may include an electrical sensor, an ultrasound head, a fiber optic viewing head, an electrical stimulator, an electrical or laser ablator, an ionic sensor, an oxygen or carbon dioxide sensor, an accelerometer, a blood pressure or temperature sensor or a cryogenic probe. In general the catheter will include leads, light guides, wave guides, etc. for energizing the active portion in response to commands of an operator.

The position and orientation of the distal end of the catheter is ascertained by determining the position of the locating sensor. In a preferred embodiment of the invention, the locating sensor comprises two or three antennas, for example coils which are irradiated by two or three radiators 18, 20 and 22, which are outside the body surface 23 of the patient.

It should be understood that placement of the radiators, as well as their size and shape, will vary according to the application of the invention. Preferably the radiators useful in a medical application comprise wound annular coils from about 2 to 20 cm in diameter (O.D.) and from about 0.5 to 2 cm thick, in a coplanar, triangular arrangement where the centers of the coils are from about 2 to 30 cm apart. Bar-shaped radiators or even triangular or square-shaped coils could also be useful for such medical applications. Moreover, in instances where a prone patient will be the subject of a procedure involving the instant technology, the radiators are preferably positioned in or below the surface upon which the patient is resting,

substantially directly below the portion of the patient's body where a procedure is being performed. In other applications, the radiators may be fairly close to the skin of the patient.

The three radiators are driven by a radiator driver 24, preferably in a manner described below, and the signals received by the receiving antennas are amplified and processed, together with a representation of the signals used to drive radiators 18, 20 and 22, preferably in the manner described below, in a signal processor 26 to provide a display or other indication of the position and orientation of the distal end 15 on a monitor 27.

Radiators 18, 20 and 22 may be arranged in any convenient position and orientation, so long as they are fixed in respect to some reference frame, and so long as the radiators are non-overlapping, that is, there are no two radiators with the exact, identical location and orientation. When driven by radiator driver 24, the radiators generate a multiplicity of distinguishable AC magnetic fields that form the magnetic field sensed by receiving antennas in the locating sensor.

The magnetic fields are distinguishable with regard to the frequency, phase, or both frequency and phase of the signals in the respective magnetic fields. Time multiplexing is also possible.

In practice the active end of the catheter may be used to gather information, such as ultrasound echo information, electrical activity information etc., and optionally to perform certain procedures on the arteries (or veins) or within an organ chamber 28 to which the artery (or vein) leads. Particular examples of organ chambers are the chambers of the heart, brain or gastrointestinal tract. It is a particular object of some aspects of the present invention to more accurately map the electrical activity of the heart and to more accurately image the walls of the heart, as will be described in more detail below.

Fig. 2 shows a schematic illustration of a preferred embodiment of the distal end of catheter 10. A graphic illustration of locating sensor 14 is shown in Fig. 3. Sensor 14 preferably includes two or more and more preferably three sensor coils 30, 32 and 34 wound on air cores. In a preferred embodiment of the invention the coils have mutually orthogonal axes, one of which is conveniently aligned with the long axis of the catheter. Unlike prior art location sensors (used for other applications) which contain three coils that are concentrically located, or at least whose axes intercept, the coils of the preferred embodiment of the invention are closely spaced along the axis of the catheter to reduce the diameter of the locating sensor and thus make the sensor suitable for incorporation into a catheter.

For most aspects of the present invention, quantitative measurement of the position and orientation of the catheter distal end relative to a reference frame is necessary. This requires at least two non-overlapping radiators that generate at least two distinguishable AC magnetic fields, the radiators' respective positions and orientations relative to the reference frame being known; a radiator driver which preferably continuously supplies the radiators with AC signals to generate the AC magnetic fields; and a location sensor, consisting of at least two non-parallel sensors to measure the magnetic field flux resulting from the at least two distinguishable magnetic fields. The number of radiators times the number of sensors is equal to or greater than the number of degrees of freedom of the desired quantitative measurement of the position and orientation of the sensors relative to the reference frame.

Since, in a preferred embodiment of the invention it is preferred to determine the six position and orientation coordinates of the distal tip of the catheter, at least two coils are required in location sensor 14. Preferably three coils are used to improve the accuracy and reliability of

the position measurement. In some applications where fewer dimensions are required, only a single coil may be necessary in locating sensor 14.

Leads 36 are used to carry signals detected by the sensor coils to signal processor, via the proximal end of the catheter, for processing to generate the required position information. Preferably, leads 36 are twisted pairs to reduce pick-up and may be further electrically shielded.

In a preferred embodiment of the invention, coils 30, 32 and 34 have an inner diameter of 0.5 mm and have 800 turns of 16 micrometer diameter to give an overall coil diameter of 1-1.2 mm. The effective capture area of the coil is preferably about 400 mm^2. It will be understood that these dimensions may vary over a considerable range and are only representative of a preferred range of dimensions. In particular, the size of the coils could be as small as 0.3 mm (with some loss of sensitivity) and as large as 2 or more mm. The wire size can range from 10-31 micrometers and the number of turns between 300 and 2600, depending on the maximum allowable size and the wire diameter. The effective capture area should be made as large as feasible, consistent with the overall size requirements. While the preferred sensor coil shape is cylindrical, other shapes can also be used. For example a barrel shaped coil can have more turns than a cylindrical shaped coil for the same diameter of catheter. Also, square or other shaped coils may be useful depending on the geometry of the catheter.

Leads 38 are used to power active portion 16 and/or to receive signals therefrom. The nature of leads 38, which may vary and may, for example, include an optical waveguide or other transmission media as appropriate to their task.

For example, an electrode located on the distal tip of the catheter records local cardiac electrical activity, for example, on the endocardium. These local electrograms (ECG's) are transferred via leads 38 to the proximal end of the catheter and fed into an ECG amplifier. The amplified

ECG signals are transferred to the control system that presents to the physician the local electrogram morphology acquired from the site whose location was determined at the same time.

Figure 4 is a block diagram of preferred circuitry used in computing the position of locating sensor 14. In this exemplary embodiment, three radiators 18, 20 and 22 and three sensor coils 30, 32 and 34 are used. Radiator driver 24 provides distinguishable, simultaneous AC current signals to each radiator. Control circuitry 40 utilizes D/A convertors 42, 44 and 46 to generate three sine waves of three different frequencies, f_1, f_2 and f_3, which are output separately to signal amplifiers 48, 50 and 52.

In order to achieve a fast response locating system the use of slow responding filters has been eliminated by using cross-correlation of the radiated and the received signals. This cross-correlation is performed over a window in time which contains an integer number of the cycle lengths of the three radiated signals. Use of an integer number of cycles generally results in a decrease in processing errors and a more accurate determination of the relative amplitude and phase of the signals received by the sensor coils. If non-integral cycle lengths are used an error in the cross-correlation generally results, unless a very long correlation window is used.

If a short correlation window is used, (the shortest is the minimal common product of the cycle times), the ratio between frequencies should be a rational number. The frequency of a radiator c, f_c, where c = 1, 2 or 3 should satisfy the equation:

$$f_c = n_c \cdot f_b \qquad (1)$$

where n_c is any positive integer such that n1 $\neq$ n2, n2 $\neq$ n3, and n3 $\neq$ n1, and f_b is an arbitrary base frequency to assure that integral cycle lengths can be used for cross-correlation.

The radiating driver amplifier output signals are

delivered to the radiators through current sensitive circuitry 54, 56 and 58, such as a resistor, loop or more sophisticated circuitry as is known in the art. The current-sensitive circuitry produces an output which represents the amplitude and phase of the driving signal for the radiators and which is passed to signal processor 26. With this arrangement, the three radiators will generate a magnetic field composed of three differently oriented field components each having a different known frequency. Each of these field components will be sensed by each of sensor coils 30, 32 and 34 which will each produce a signal composed of three frequency components having different amplitudes and phases depending on the relative distance and orientation of the particular sensor coil and particular radiator which radiates a particular frequency.

The outputs signals of sensors 30, 32 and 34 are amplified in amplifiers 60, 62 and 64 respectively and passed on to signal processor 26.

Fig. 5 shows in expanded detail the basic flow chart representing a control sequence and its application to the circuitry of Fig. 4. During the initialization phase, indicated by block 66, the frequencies of the three sine waves, the physical position and orientation of radiators 18, 20 and 22 in respect to a reference frame, the properties of the radiators and sensors and the coordinates of a single point in the mapping field are defined. Sine waves having respective frequencies f_1, f_2 and f_3 are synthesized as indicated by block 68, for example in control 40. These generated frequencies are transmitted, preferably continuously, by radiators 18, 20 and 22 as indicated by block 70 and as described above with reference to Fig. 4. The control sequence enters a timing loop 72 that periodically sends signals to activate the signal processor to cross-correlate the coil sensor signals with the radiated signals and to calculate the orientation and position of locating sensor 14 relative to the reference frame.

Both analog and digital embodiments of signal processing are possible in accordance with preferred embodiments of the invention. These different approaches can be modified in a variety of ways by those skilled in the art, and can be combined in different modes in order to practice them simultaneously. Some applications of the present invention would benefit from the digital approach, while the analog approach may be the preferable solution in other cases.

The digital embodiment is described in conjunction with Fig. 6, which is a functional block diagram of signal processor 26. The inputs to the processing block are the signals from amplifiers 60, 62 and 64 (the sensor coil signals) denoted by SIG and inputs from current sensing circuits 52, 56 and 58 denoted as CUR. In this embodiment the six input signals are converted from analog to digital signals by an array of A/D converters 74. The sampled digital signals are passed to the "calculate cross correlation" block 76, which may consist of dedicated circuitry or which may be performed by a dedicated or shared microprocessor. Using the six data streams (three AC currents flowing through the radiators and three sensor readings) the cross correlation elements can be calculated using the following method:

Given that

SIG_s is the amplified output of sensor s, where s = 1, 2 or 3;

CUR_c is the current flowing through radiator c, where c= 1, 2 or 3;

f_b is an arbitrary base frequency;

f_0 is the sampling frequency which is an integral multiple of f_b; and

and N is the correlation length in number of samples, $N=K(f_0/f_b)$, where K is any positive integer,

the correlation between CURc and the sine wave of frequency

f_C is:

$$A_C^I = (2/N)\cdot\sum CUR_C[i]\cdot\sin(2\pi f_C(i/f_0)); \quad (3)$$

and the correlation between CURc and the cosine wave of frequency f_C is:

$$A_C^Q = (2/N)\cdot\sum CUR_C[i]\cdot\cos(2\pi f_C(i/f_0)); \quad (2)$$

where both summations are taken over i from 1 to N.
The correlation between SIG_S and the sine wave of frequency f_C is

$$B_{S,C}^I = (2/N)\cdot\sum SIG_S[i]\cdot\sin(2\pi f_C(i/f_0)); \quad (4)$$

and the correlation between SIG_S and the cosine wave of frequency f_C is

$$B_{S,C}^Q = (2/N)\cdot\sum SIG_S[i]\cdot\cos(2\pi f_C(i/f_0)); \quad (5)$$

where both summations are taken over 1 from 1 to N.

A preferred ratio of f_1, f_2 and F_3 is 1, 2, 3 and preferred frequencies are 1, 2 and 3 kHz. The useful frequency range is believed to lie between 50 Hz and 50 kHz.

The calculation of the fields and currents, designated by block 78, can also be performed using either dedicated circuitry or a dedicated or shared microprocessor. The amplitude of the current through each radiator A_C can be calculated using:

$$A_C = |A_C^I + jA_C^Q| \quad (6)$$

and the magnitude of the field generated by each radiator, $|B_{S,C}|$, can be calculated using:

$$|B_{s,c}| = |B^{I}_{s,c} + jB^{Q}_{s,c}| \quad (7)$$

The phase between the current in radiator c and the field sensed by sensor s, $\Psi_{s,c}$, is

$$\phi_{s,c} = \arg(B^{I}_{s,c} + jB^{Q}_{s,c}) - \arg(A^{I}_{c} + jA^{Q}_{c}) - \Psi^{0}_{s} \quad (8)$$

where Ψ^{0}_{s} is the phase delay between the radiated field and the field as read by sensors s. The amplitude of the field generated by radiator c as sensed by sensor s is:

$$B_{s,c} = |B_{s,c}|, \quad \text{if } |\phi_{s,c}| < 90° \quad (9A)$$
$$B_{s,c} = -|B_{s,c}|, \quad \text{if } |\phi_{s,c}| \geq 90° \quad (9b)$$

The magnetic field for every possible location and orientation of the sensor in the mappable space can be obtained by using:

1) The field equations of the radiators used in a specific embodiment,

2) The exact position and orientation of the radiators, and

3) The current flowing through the radiators A_c.

Preferably the contributions of each field generator are used to solve a set of field equations, which are dependent upon the field form. Solving these equation sets produces the location and orientation of the remote sensors, most preferably simultaneously.

More particularly, the field equations are derived specifically for each embodiment and are dependent on the geometry and characteristics of the radiators. In the preferred embodiment of the invention where the radiators are coils, the field equations can be described as follows:

For a coil with N turns a radius R and a current I, the radial field component at a distance r is

$$B_r(I,\vec{r},\cos\theta)=(2\pi R^2 10^{-7}\cdot NI/r^3)\cdot$$

$$\sum(2i+1)P_{2i}(0)\cdot(R/r)^{2i}\cdot P_{2i+1}(\cos\theta) \quad (10)$$

and the tangential field component is:

$$B_\theta(I,\vec{r},\cos\theta)=(2\pi R^2 10^{-7}\cdot NI/r^3)\sum P_{2i+2}(0)(R/r)^{2i}P^1_{2i+1}\cos\theta$$

where the sums are from 1=0 to i=∞ and where $P_n(x)$ is a Legendre Polynomial of degree n, and calculated recursively by:

$$P_0(x) = 1$$
$$P_1(x) = x \quad (12)$$
$$P_n(x) = 1/n\ [(2n-1)\ x\ P_{n-1}(x) - (n-1)\ P_{n-2}(x)]$$

$P^1_n(x)$ is a generalized Legendre Polynomial of degree n, and calculated by:

$$P^1_n(x)= -(n+1)\cdot x\cdot(P_n(x) - P_{n-1}(x))/(1-x^2)^{\frac{1}{2}} \text{ for } |X| < 1$$
$$= 0 \quad \text{for } |X| = 1 \quad (13)$$

These field equations are correct for r>R for a radiator located in location $\vec{P}$. The field induced at location $\vec{K}$ is, as shown in Fig. 7, given by:

$$B = B_u\hat{O} + B_w\hat{W}$$
$$B_w = B_r\sin\theta + B_\theta\cos\theta \quad (14)$$
$$B_u = B_r\cos\theta - B_\theta\sin\theta$$

where $\hat{O}$ is a unit vector in the radial direction of the radiator located at $\vec{P}$ and $\hat{W}$ is a unit vector in the tangential direction of the radiator located at $\vec{P}$. Using this general field equation one can calculate the field at point $\vec{K}$ generated by each of the radiators.

The remote sensor orientation, denoted by $\hat{V}$ determines the field sensed by this sensor at this location ($\vec{K}$).

$$\vec{B}\cdot\hat{V} = B_{\hat{V}} \quad (15)$$

Therefore the field sensed by a remote sensor is

$$B_{\hat{V}} = B(\vec{P}, \hat{O}, I, \vec{K}, \hat{V}) \qquad (16)$$

where $\vec{K}$ and $\hat{V}$ are the unknown variables, and $\hat{O}$, $\vec{P}$ and I are the known variables for any given coil.

In the example embodiment there are three radiators; therefore there will be three known values of $\vec{P}$ and three known values of $\hat{O}$. The three sensors have a fixed and known location and orientation in the remote object reference frame. For each position and orientation of the remote object, one can compute the location and orientation of each sensor in the radiator reference frame and therefore compute the field sensed, B_V, for each radiator and each sensor. In the case of the present location system, each field sensed by each sensor from every radiator is measured and the field equations are solved to obtain the location and orientation of the remote object (x, y, z, $\varepsilon, \xi,$ and ζ).

The results of this approach for the three radiator, three sensor system used here as an example, are nine non-linear algebraic equations with six variables (namely, x, y, z of the sensing means position and $\varepsilon, \xi,$ and ζ for the location sensor orientation) in the form of:

$$([F_{s,c}\,(x,y,z,\varepsilon,\xi,\zeta) = B_{sc}]_{s=1,2,3})_{c=1,2,3} \qquad (17)$$

In this embodiment of the invention, the nine sensor readings ($B_{s,c}$) are the measured quantity, and by solving this overdetermined system of equations (using a variety of known numerical methods such as the Newton-Raphson method for non-linear systems of equations or Multidimensional Secant Methods, specifically Broyden's method), the location and orientation of location sensor 14 is determined. A description of several possible numerical methods for solving such a set of equations is found in William H. Press et al, "Numerical Recipes in C. The Art of Scientific Computing", second edition, Cambridge University Press,

1992. The location sensor position and orientation are displayed on monitor 27.

An ECG monitor may be used to synchronize the acquisition of the signals from the sensor coils so as to remove cardiac motion artifacts from the position information. Furthermore, a reference sensor may be attached to a portion of an organ being tested or treated, such as the heart, which will be used to correct for breathing motion or patient movement. In this way, the acquired sensor positions may be referenced to the organ structure and not to an absolute outside reference frame, which is less significant.

In an analog based embodiment of signal processor 26, some of the parameters are calculated using analog circuitry. Fig. 8 is a schematic of one analog based embodiment of signal processor 26. In this embodiment, three sine and three cosine wave signals of frequency f_1, f_2, and f_3, are used in addition to the SIG and CUR signals used in the embodiment of Fig. 6. The SIG and CUR signals are filtered by 12 phase sensitive filters (correlators) 80, such as are shown in Fig. 9 to produce signals indicative of the sine and cosine components of the SIG and CUR signals.

These analog signals are then passed to a set of A/D converters 82. The fields and currents and positions are calculated in the same manner as described above with respect to Fig. 6.

Fig. 9 shows the expanded view of one possible embodiment of one of the analog filter elements of Fig. 8. Each analog filter unit has three inputs; a cosine wave $\cos(2\pi f_C)$, a sine wave $\sin(2\pi f_C)$, and the signal, either one of SIG_S or CUR_S from which the frequency component f_C is to be extracted. Within the analog filter unit the signal is multiplied by $\sin(2\pi f_C)$ and $\cos(2\pi f_C)$ in multipliers 84 and 86. The results are passed through low pass filters 88 and 90 to obtain the desired components of the signal.

The description above primarily concerns acquiring

information by a set of two or more sensors that is used to determine the position and orientation of a remote object or a point on a remote object such as a medical device or instrument. It is also within the scope of the invention that a remote object will have more than one set of sensors, preferably from 2 to 6 sets of sensors, that will provide sufficient parameters to determine the shape and/or configuration of a remote object, preferably relative to a reference frame. For example, if the catheter has additional sets of sensors located proximal to its distal tip, it would be possible to determine the shape and/or configuration of portions of the catheter. Similarly, for another invasive procedure such as a sigmoidoscopy or colonoscopy, it may be possible to determine the shape and/or configuration of some or all of the scope used.

The equipment necessary to practice the invention is mostly conventional. In one embodiment of the invention, the controller is a simple off-the-shelf 486 IBM compatible computer. The A/D boards are commercially available and have the characteristic of being able to sample at least 8 channels with a sampling frequency of between 500 - 40,000 samples per second on each channel. An example of such an A/D Board is the National Instruments AT-MIO-16X that is available from National Instruments, Texas, USA. The D/A function is achieved using commercially available 8-21 bit resolution D/A boards. Examples of such a D/A are the National Instruments A/D,D/A Board AT-MIO-16X or National Instruments DSP model AT-DS2200. The radiation driver amplifiers are commercially available, with 2-16 ohms output impedance and an output power of 60-500 watts. An example of such amplifiers is the Inkel amplifier type NA-420, from Inkel of Seoul, Korea. The radiators are also commercially available and have the following characteristics: 1-6 cm radius, 0.5-3 cm thickness, and 100-500 turns made of copper wire of diameter 0.1 -0.95 mm. A specific example of such a coil could be coils having a 4

cm radius, 1 cm thickness with 151 turns of copper wire of 0.41 mm diameter.

While the sensor described above is preferred, other sensors may be suitable for some applications, such as Hall effect sensors, for example those available from Allegro Micro Systems, Inc., USA or magneto-resistor sensors, sensors, flux gate magnetic sensors, and/or other magnetic flux sensors.

Controller 40 represents an assemblage of units to perform intended functions. For example, such units may receive information or signals, process information, function as a controller, display information, and/or generate information or signals. Typically controller 40 may comprise one or more microprocessors.

In accordance with a preferred embodiment of the invention, active portion 16 of catheter 10 is a forward looking ultrasound send/receive transducer. Such a transducer can give a one-dimensional map of the acoustic properties of the material lying in front of it by radiating a focused beam of pulsed acoustic energy and then measuring the echoes of the beam reflected by changes in acoustic properties along the path of the beam. In order to provide a three dimensional image it is necessary to change the direction of the beam, preferably without changing its position by a great amount.

In particular, such a steerable, one dimensional acoustic transducer can be used to map the heart walls or blood vessels, ultrasonically, from inside the heart. When coupled with a reference location sensor at a reference point on the heart and ECG gating of the acoustic pulses, such a transducer can generate the information required to form a three dimensional image of the heart or blood vessels or any other organ, at one or several different phases of the heart cycle.

The principle of two preferred embodiments of a steering mechanism are shown in Figs. 10A-10D and 11

respectively. Fig. 10A shows a steering mechanism 92 that fits into the distal end of a catheter and comprises two steering wires 94 attached to a steering head 96. Head 96 is formed of a relatively flexible material such as stainless steel and is slit along its axis, each side of the split being attached to one of wires 94. Such a head may be manufactured by attaching two wires (94) at their end and then flattening the wires to form a more easily bent structure.

Attached to the distal end of the steering head is a relatively rigid housing containing locating sensor 14 and active portion 16 which, in the present preferred embodiment, is an ultrasonic send/receive transducer. At least head 96 and wires 94 are encased in a catheter sheath 104 which is not shown in Figs. 10A-10C for clarity of presentation. This steering mechanism can also be used for other active portion types such as for electropysiologic mapping procedures and for improved steering of catheters or many types, with or without location sensing.

In Fig. 10B one of wires 94 has been shortened as compared with the other wire. Since the catheter sheath holds the wires together, the result of such shortening of one wire is bending of the head, which is facilitated by the axial slit. Locating sensor 14 and active portion 16 are rigidly attached so that measurement of position and orientation of the locating sensor will give the position and orientation of the active portion (ultrasound transducer). By varying the angle of bending and rotating the catheter, imaging over nearly 360° image can be achieved. Additionally or alternatively, as shown in Fig. 10C, the amount of rotation can be reduced by shortening the other wire and which causes bending in the other direction. Slight motion of the transducer can be corrected by a simple translation of the acquired one dimensional image associated with the particular position.

Fig. 10D shows a mechanism 98 placed at the proximal

end of the catheter for changing the relative lengths of wires 94. A handle 100 comprises a housing 102 to which catheter sheath 104 is attached. The proximal end of wires 94 are formed in a loop (for example by welding the ends of the wire) and wrapped around a spindle 106 which is preferably fixed and which forms a frictional contact with the wires.

A lever 108 is rotatably attached near its center at a pin 110 to the housing and is attached at one end to wire 94 and at the other end to a slider 112 which is slidable parallel to the housing. When the slider is moved, one of the wires 94 at the distal end is lengthened with respect to the other.

Fig. 11 shows the distal end of a catheter having an alternative steering mechanism. A relative rigid sleeve 114 is placed within cathode sheath 104. Sleeve 114 can be axially displaced relative to the sheath from the proximal end of the catheter.

The distal end of sleeve 104 is formed with a disk 116 through which a relatively less rigid wire 118 passes. Wire 118 is formed with a permanent bend near its distal end at which end, position sensor 14 and active portion 16 are attached. Axial movement of sleeve 104 straightens wire 118 resulting in a change in orientation of both the position sensor and the active portion. If wire 118 is sited off axis, then rotating the wire will rotate the catheter.

It should be understood that steering of acoustic beams may also be achieved by a moving mirror or by a phased array ultrasonic transducer, and that such a mirror or other arrangement may be present in the active portion. Such active scanning may supplement or replace the passive steering provided by the mechanisms of Figs. 10 and 11.

Fig. 12 shows a simplified system block diagram of ultrasonic acquisition and image formation in accordance with a preferred embodiment of the invention. An image sensor 120, such as the ultrasound sensor described above,

transmits an acoustic pulse 122 in response to a signal received from a transmitter driver circuit 124. An acoustic echo 126 (generally comprising several echoes) is received by the image sensor which produces an echo signal, which when amplified, is sent to a receiver processing circuit 128 which generates a one dimensional "image" at its output 130. Information identifying the heart phase of the image may also be present at output 130 which may comprise a plurality of output ports. In one embodiment of the invention, especially useful for heart imaging, the acquisition of the image is made in response to signals received from an ECG monitor 132. This allows for acquisition of images at a particular portion of the heart cycle so that the various one-dimensional images can be easily reconstructed into a three dimensional image.

In particular, if the most significant echo is used as the measure of the distance from the ultrasonic sensor to the chamber along the measurement direction of the sensor, then the collection of such distances (referenced to a reference point in the chamber) will allow the reconstruction of the surface morphology.

Fig. 13 shows a simplified block diagram of a three dimensional image reconstruction system which utilizes a series of one dimensional images generated by the circuitry of Fig. 12 and continuous sensed location and orientation information generated by the position locator and its associated circuitry as described above. In general it is useful to acquire the sensed location and orientation to coincide with the acquisition of each one-dimensional image. One of the various methods described above for steering the distal tip of the catheter is used to acquire a plurality of one dimensional images with a plurality of orientations. An automatic mechanism may be used to continuously change the orientation of the imaging head in accordance with the principles of Figs. 10 and 11 and to rotate the catheter so that operator intervention is not required.

An image reconstruction processor 132 orients and references the individual one dimensional images in accordance with the sensed location and orientation information and forms a 3-D image which can be presented on an image display 13 either in the form of a series of two dimensional slices or a full three dimensional reconstruction. When images at different points in the heart cycle are acquired, the image displayed may be a cine image of the reconstruction.

In a preferred embodiment of the invention a two dimensional image is acquired by the ultrasound sensor which can be a phased array of acoustic crystals of a single crystal in conjunction with a mirror rotating about an axis that deflects the ultrasonic beam in a predetermined path.

In a preferred embodiment of the invention active portion 16 comprises a sensor for sensing electrical signals generated at selectable positions on the heart. As described below, such sensings of electrical signals can be used to map the electrical activity of the heart. The active portion may also include an electrode useful for pacing the heart and/or for ablating a portion of the heart. Such ablation is especially useful in the treatment of the most common lethal cardiac arrhythmia, ventricular tachycardia (VT), i.e., very rapid and ineffectual contractions of the heart muscle. VT is the cause of death of approximately 300,000 people annually. It is also useful in the treatment of other arrhythmias.

A catheter useful for electrical mapping of the heart/ablation is shown schematically in Fig. 14.

Active portion 16 comprises a conducting tip, preferably of platinum, having a length of between 1-12 mm, preferably about 2 mm. The tip is connected via a tip electrode lead-in wire 138 to a switch at the proximal end of the cathode which switches the tip to a source of voltage for pacing or/ablating or to a detector for detecting electrical signals generated by the heart. A conducting ring

electrode 136 is placed, proximal to locating sensor 14, on the outside of catheter sheath 104 and is connected to ground or to a recorder via a return lead 140. When used for pacing, as described below, a 1-10 ma pulse is applied between tip 16 and ring electrode 136. When used for ablation RF energy at about 0.5 MHz and 10-100 V is applied for 10-200 sec.

Locating sensor 14 is rigidly attached to the tip and the sensor and tip may be manipulated by an eccentric wire 142. The twisted wire leads are preferably shielded by a shield 144 to reduce pickup from the relatively high voltages carried by leads 138 and 140.

Preferably, an electrically insulating heat shield 146 is placed between the tip and the locating sensor.

Fig. 15 is a schematic block diagram for acquiring a basic electrocardiogram map in accordance with a preferred embodiment of the invention. Using a transesophageal echocardiograph in the preferred embodiment, a multiplane image of the heart chambers is acquired prior to the mapping study. The image is acquired only during a fiducial point in time during the cardiac cycle. In the preferred embodiment, the image is acquired at end-diastole in response to an end diastole synch-signal. A three-dimensional image of the heart chambers is reconstructed indicating the endocardial morphology and the location of one or more reference catheters within the heart chamber. This image can be acquired by a 3-D transesophogal ultrasound image, by a CT scanner, by an MRI scanner or by other imaging techniques. The image can also be constructed by touching the catheter to the surface of the chamber (endocardium) in a number of places and measuring the positions. These points can then be used to describe a thee dimensionsional surface which represents the chamber surface.

In the previous PCT and US applications (PCT/US94/08352 filed July 20, 1994 and 08/094,539 respectively), in which

fewer than six location and orientation values were determined, reference locatable catheters were place at three positions in the heart to form a reference plane against which the position of the active catheter was referenced. Preferably, these reference locatable catheters were placed, for example, in the right ventricular apex, the right atrial appendage, and the pulmonary artery at the level of the pulmonary valve, respectively. When a reference catheter having a location sensor 14 as described hereinabove is used for reference purposes, only a single sensor is required to define the relative location and orientation of the mapping catheter. While any of these locations can be used, it is presently preferred to place the reference sensor in the distal coronary sinus.

Fig. 16 is a schematic block diagram for illustrating the computerized endocardial activation mapping algorithm (used during sinus rhythm mapping and during ventricular tachycardia mapping). A visible or audible indicator preferably indicates the beginning of a data point acquisition. Both electrical activity and location/orientation data are acquired for each point in the map.

The acquisition of catheter location information is shown in left branch of the block diagram of Fig. 16. The mapper electrode is in steady and stable contact with the endocardium. Stable contact is determined by measuring the stability of the location reading, the stability of the sensed electrograms and the impedance of the contact.

The position and orientation of the locating sensor in the mapping catheter are determined continuously in accordance with the method described above and are saved in response to an end diastole synch signal. The mapper catheter tip is localized relative to the reference catheter by finding the difference in each of the six dimensions of the location and orientation. Generally speaking, for the present application the orientation of the mapper cathode is

not required, however, it must be acquired to properly transform its location and orientation to an internal heart coordinate system.

Simultaneously, the activation time of the heart at the mapper cathode tip is determined as shown on the right side of Fig. 16. First the local electrocardiogram at the tip of the mapper catheter is acquired and the activation time is calculated based on comparing the amplitude and slope of the local electrocardiogram to a template or manually by the user. The local activation time is then defined with reference to the activation time measured by an ECG terminal on the skin of the patient.

The process of data acquisition can be terminated by the user, or can be evaluated by an "evaluate activation map" algorithm described below, that examines the already acquired activation map for the density of information relative to the spatial gradient of activation times. This algorithm can indicate the next preferable site for activation time detection. The catheter is moved by the user to the new site, and the process of mapping continues.

During VT a data point is determined about every 4 to 6 heart beats. Thus, approximately 15 to 25, typically about 20, data points can be determined each minute.

Fig. 17 is a schematic block diagram for illustrating the computerized pace mapping algorithm. A visible or audible indicator indicates the beginning of a data point acquisition. Acquisition of position information is similar to that for Fig. 16 except that the average mapper location in the previous n heartbeats (n is the moving average window duration) is calculated.

The right side of Fig. 17 shows the determination of the ACI (AutoCorelation Index) in a pace mapping mode.

In a "pace mapping mode" an ECG processor acquires ECG data while the patient's heart is paced by an external source at a rate similar to the patient's arrhythmia cycle length. The ECG data is also acquired from the body surface

electrograms, and the signals are stored as a segment of ECG with a length of several cycles. The signal acquired is subjected to automatic comparison with the patient's own VT signal (see Fig. 18). The comparison between arrhythmia morphology and paced morphology is performed in two stages: First, the phase shift between the template VT signal and the paced ECG morphology is estimated using minimal error or maximal cross-correlation for two signals. Then, using this phase shift estimated from an index ECG channel, the similarity of the VT and the paced ECG morphology is measured as the average of the cross-correlation or the square error of the two signals of all channels recorded.

This two-stage calculation is repeated each time using a different ECG channel as the index channel for determining the phase shift.

At the end of this procedure the minimal error or the maximal cross-correlation found will be reported to the operator as the ACI of this pacing site.

Fig. 18 is a schematic block diagram illustrating an algorithm used to calculate the cross-correlation index while pace-mapping in accordance with a preferred embodiment of the invention. Body surface ECG data is acquired at two stages. First, during spontaneous or pacing induced VT, and second, during pacing the endocardium at different sites. The ECG data acquired during VT are signal averaged, and a template is constructed (T_{ch}, for each channel recorded). During endocardial pacing the ECG data is acquired, and the same number of beats (N) is acquired to calculate the signal averaged QRS (P_{ch}, for each channel recorded). The algorithm then calculates the phase shift between P_{ch} and Tch, which yields for the first channel the maximal cross-correlation. This time shift is used to shift the remaining channels and calculate for them the cross-correlation. All cross-correlations for all channels are summarized and stored. The algorithm then uses the next channel recorded to calculate the time shift that will cause maximal cross-

correlation in this channel. Now this time shift is applied for all cross-correlations between P_{ch} and T_{ch}, and again all cross-correlations are summarized. This procedure is repeated for all channels, and the maximal cross-correlation achieved is used as the value of the cross-correlation of the T_{ch} and the P_{ch} at this site on the endocardium.

FIG. 19 is a schematic block diagram for illustrating the output configuration of the present embodiment. A quasi-static picture of the heart chambers is presented as 3-D reconstruction of a basic image acquired prior to or during the study as previously described. Superimposed on the image is the location of the mapping/ablation catheter (corrected for the movement of the reference catheter) and the current and previous information acquired from the mapping study. This information may include, when appropriate, the activation times (presented using a color code at each acquisition site) or cross-correlation index (ACI) for each point in the pace map. Furthermore, the map can represent in the color coding the duration of the local electrograms, the presence of fragmented activity as well as various other variables calculated by the electrophysiologic processor.

The above principles can be applied for mapping other structures of the body, for example, of the urinary bladder, brain, or gastrointestinal tract. Dependent upon the examination technique, the catheter may be replaced by a needle whose tip is the locatable sensor port.

At each stage (sinus rhythm mapping, pace mapping and VT mapping) after each data point is acquired, all available information is reassessed for two purposes: first, to suggest to the operator the next site for data acquisition, and second, to test the available information to propose a site for ablation.

Two algorithms are running simultaneously to perform this procedure:

(1) Mapping guidance algorithm. This algorithm uses as

an input the available mapped information of a certain variable (e.g., local activation time during sinus rhythm). The algorithm calculates the spatial derivative of the mapped variable (i.e., activation time in this example) and calculates the next best location for adding another data point when the objective function is regularizing the spatial gradients of the mapped variable. For example, this algorithm will suggest that more data points be acquired in areas in which the mapped variable is changing significantly over a short distance.

The location suggested by the algorithm is be presented to the operator as a symbol on the display. The same display already shows the basic image of the heart chamber and the current location of the mapping/ablation catheter. Therefore, the operator will move the mapping/ablation catheter to reach the suggested location for further data acquisition.

This algorithm is most beneficial during VT mapping, where the available time for data acquisition is limited by the adverse hemodynamic effects of the arrhythmia. Therefore, such an algorithm which examines the available data points of a map in real-time and immediately suggests the next site for acquisition is very useful.

(2) Prognosing likelihood of successful ablation algorithm. This algorithm is a user-defined set of hierarchical rules for evaluating the acquired information such as the rules given immediately below. The operator is expected to grade the importance of the specific information acquired in the mapping/ablation procedure, as to its likelihood to identify the correct site for ablation.

Grading of mapping results suggesting the likelihood of successful ablation at that site (A = highly likely successful and D = least likely successful):

(a) The identification of a typical re-entrant pathway on VT mapping with an identifiable common slow pathway - Grade A;

(b)The identification of a site with over 90% correlation index in the pace map - Grade B;

(c) The identification of a site where VT was terminated with a non-capture premature stimulus - Grade C; and

(d) The identification of pre-potential maps recorded during VT, which are similar to diastolic potential maps recorded during sinus rhythm - Grade D.

Other types of electrographic maps of the heart are also possible. By use of variables determined from paced or non-paced acquisitions of electrographic data, the following additional maps can be generated:

(1) Sinus rhythm activation map (isochronal map);
(2) Diastolic potential occurrence time map
(3) Local latency isochronal map during pace mapping;
(4) Activation time isochronal map during VT; and
(5) Pre-potential isochronal map during VT mapping.

Also, the sites where VT was terminated by a non-captured premature stimulus can be presented.

The acquisition of these maps and of other factors suitable for mapping and procedures for their determination as well as additional details of the above mapping procedures can be found in the above mentioned U.S. Patent Application Number 08/094,539 and PCT Application PCT/US94/08352.

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URGENT

October 6, 1996

European Patent Office
International Preliminary Examination Authority
Attention: Mr. M. R. Stern (Bayerstrasse office)
Erhardtstrasse 27
D-80298 Munich, Germany

Re: PCT Application PCT/US95/01103; Medical Diagnosis, Treatment and Imaging Systems; Our Ref. 20885

Dear Mr. Stern,

Further to our meeting of September 26, 1996, I enclose a new set of claims and a letter accompanying the new claims which sets forth our arguments concerning patentability, new matter and examinability (with respect to claims 37-39) of the claims. The claim set includes all the changes which we discussed at our meeting and other amendments as described in the accompanying letter.

I believe that you will now find that, in view of the amendments to the claims and the accompanying letter, you will be able to issue a positive IPER in this application. We would greatly appreciate your comments as to unity of invention as it would be viewed from the perspective of the EPO in the national stage. This will enable us to file European applications in an efficient manner.

Sincerely,

Paul Fenster

Dr. Paul Fenster
Patent Attorney
Sanford T. Colb & Co.

Application Number: PCT/US95/01103

Title: MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

Filing Date: January 24, 1995

Applicant: Biosense, Ltd.

LETTER ACCOMPANYING AMENDMENT

This communication is in response to a written opinion dated July, 9 1996 in the above referenced application. This letter is accompanied by new claims 1-68 contained on replacement pages 40-49. Page 50 is canceled. Claims 1, 29, 33 and 40 have been amended. Claim 58 and 59 have been canceled and the succeeding claims have consequently been renumbered. The following discussion refers to the claims as now numbered. References to the specification are to the published version thereof.

The applicants thank, Mr. Stern, the Examiner in charge of the application for the courteous interview granted to Dr. Shlomo Ben-Haim, one of the inventors and applicants' agent, Dr. Paul Fenster on September 26, 1996. The following remarks and the amendments in the accompanying claims include changes to the claims agreed to at the interview.

Invention 1

The independent claims in this invention (claims 1 and 33) were rejected, in the written opinion, as being anticipated by D1. During the interview D3 was also mentioned by the Examiner as being relevant to these claims.

Both claims 1 and 33 require the computing of the six dimensions for position and orientation in response to the signals generated by the sensors. Neither D1 nor D3 teaches the finding of the six dimensions of position and orientation, inter alia since neither uses such six dimensions. In particular D1 (references are to the English language version, US 5,295,486) at col. 3, lines 55-64 (the portion cited by the Examiner) and the following paragraph describe the calculation of position using two sensors and two field induction loops. Such a system can not generate the required six dimensions. In the next following

paragraph orientation is mentioned but it is not a parameter to be measured but rather in terms of determination if some favored position or orientation is achieved. In particular, there is neither motivation nor structure in D1 for finding six dimensions of position and orientation.

Applicants have amended claim 1 to make clear that the six dimensions are calculated in response to the signals generated by the sensor coils. This is already explicit in claim 33, which has however, been amended in other respects for improved clarity.

With respect to D3, here again there is a failure of both motivation and structure. First, since the coils are all axially directed, they cannot be used determine the orientation angle about the axis of the catheter (the "roll"), which is one of the three dimensions of orientation. Furthermore, for the use described in D3 there is no need for this orientation. In fact the reference at page 2, lines 2-3 and 32-33; page 3, lines 10-11 and 21-26; and page 5, lines 5-9 and 30 et seq. describes only determination of position. Furthermore page 9, lines 20-24 and page 9, line 32 to page 16, line 16 describe the determination of the position and two dimensions of orientation.

Furthermore, there is no reason given for determining the third orientation to carry out the purposes of the reference.

For this reason neither D1 or D3 anticipate invention 1 as claimed or make it obvious.

Invention 2

Three independent claims are used to define this invention, namely claims 29, 37 and 60. These claims were rejected in the written opinion as being anticipated by D2. However, each of the claims contains limitations which are not found in the D2.

In particular, claim 29 describes manipulating the distal end of the catheter. D2 does not manipulate the distal end of the catheter but rather keeps it fixed and manipulates a transducer which is movable within the fixed catheter. Claim 37 includes the requirement that the six dimensions of position and orientation of the transducer be determined for each representation. However, D2 does not determine any position and does not determine all three orientations of the transducer. Finally, claim 60 includes

taking measurements at a plurality of positions and orientations and utilizing the measurements to form an image of a surface. D2 makes all the measurements from a single position.

The Examiner refused to examine claims 37-39 as being directed to a "surgical method of treatment." However, the claim is directed to a method of imaging and not to a method of treatment. Furthermore, no surgical activity is either explicit or implicit in claim 37, the claimed method being equally applicable to a method of imaging the colon for example. Nor, under the rules, is a surgical method of imaging excluded from examination under the PCT. The relevant PCT rule (67.1(iv)) reads: "methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods." According to this rule only surgical treatment methods are excluded. All diagnostic methods are excluded, however, medical imaging methods are not diagnostic methods, per se and are not excluded. In this regard Applicants note that there is nothing in the rules which makes any distinction between surgical and non-surgical methods of diagnosis. If surgical imaging methods are excluded as being diagnostic, then so should non-surgical imaging methods such as X-ray, CT, MRI and Nuclear Medicine imaging methods. However, long tradition sanctions such claims.

Invention 3

This invention is now represented by only one independent claim, namely, claim 58. This claim was rejected as being anticipated by D6 (Figs. 9, 10; page 5, lines 12-35; and page 14, line 21 to page 15, line 19). However, D6 does not teach at least one element of claim 58, namely, a "flat relatively flexible portion being slit alone a portion of the length thereof." The embodiment covered by this claim is shown in Fig. 10 of the present application and does not corresponding to any disclosure in D6.

Invention 4

This invention includes one independent claim, namely claim 40. Claim 40 as originally presented distinguished over the cited

prior art, D3, in that it required that the multiple field sensors be "proximate to the distal end." In D3 where two or more coils are utilized they are described as "two or more sensing coils may be mounted in spaced relationship along the length of the probe, one preferably being located adjacent the tip of the probe and the others removed from the tip." (Emphasis added.)

The dictionary defines "proximate" as being "very near," which is diametrically opposed to the teaching of D3 which requires a spacing for its proper operation.

In order to further distinguish the claim from the prior art claim 40 has been amended to add that the sensors have a fixed orientation between them. In D3, the sensors do not have such a fixed orientation. For the basis for this change see the discussion below of the "new" material rejection of claim 29 (in particular, page 25, lines 8-10).

FORMAL MATTERS

1) The Examiner suggested in the written opinion that claim 29 had been amended, in the amendment accompanying the demand under Chapter II, by adding undisclosed subject matter. Applicants disagree. As was explained by applicants' agent at the interview, the added feature is implicit from the disclosure and is clearly evident to a person of skill in the art who reads the specification. In particular, the transducer is defined at page 28, lines 16-17 as being "forward looking." Furthermore, the specification describes the requirement of changing the orientation of the device without changing its position by a great amount (page 28, lines 22-25). Additionally, the method given for changing the orientation is to change the orientation of the distal end of the catheter as a whole. Furthermore, the transducer is described as being contained in a relatively rigid housing attached to the distal end (page 29, lines 10-14). The transducer and the sensor are described as being rigidly attached "so that measurement of the position and orientation of the locating sensor will the position and orientation of the active portion" (page 29, line 24-28). Finally, on page 25, lines 8-10 the three sensors are described as having a "fixed and known

location and orientation in the remote object reference frame," a remote object being, for example, a medical instrument, such as a catheter (see page 27, lines 3-4 and 12).

From all of these statements (and from Fig. 14) it is clear that in at least some of the described embodiments the sensors are fixed with respect to the distal end of the catheter and with respect to the sensor so that the addition to claim 29 is well based on the disclosure. Applicants note that the amendment is not required for patentability (see the above discussion of Invention 2) but was added to further clarify the invention and to further distinguish it from the prior art.

2) Formal changes to the claims have been required by the examiner to place them in European form (section VII, items 1-4). Since the present application will form the basis for applications in many different countries with varying rules of claim structure and different requirements for citing prior art in the disclosure. In view of this fact applicants will defer carrying out these requirements until the National stage. At that time, the claim structure and specification will be adapted to local rules and practice. Of course, we expect that these observations will be included in the IPER.

3) Claim 1 has been amended to overcome the objection to the use of the word "point."

CLAIMS

1. A locating system for determining the location and orientation of an invasive medical instrument relative to a reference frame, comprising:

a plurality of field generators which generate known, distinguishable fields in response to drive signals;

a plurality of sensors situated in the invasive medical instrument proximate the distal end thereof which generate sensor signals in response to said fields; and

a signal processor which has an input for a plurality of signals corresponding to said drive signals and said sensor signals and which computes the three location coordinates and three orientation coordinates of a portion of the invasive medical instrument, responsive to said drive and sensor signals.

2. The locating system according to claim 1 wherein one of the plurality of field generators or sensors comprises three distinguishable, non-overlapping, generators or sensors.

3. The locating system of claim 1 wherein said plurality of field generators comprises three distinguishable, non-overlapping, generators and said plurality of sensors comprises three distinguishable, non-overlapping sensors.

4. The locating system of any of claims 1-3 wherein each sensor comprises a coil.

5. The locating system of claim 4 wherein said plurality of coils have axes which intersect within a coil.

6. The locating system of claim 4 or claim 5 wherein said plurality of coils comprises three coils and wherein said coils have axes which do not all intersect in a point.

7. The locating system of any of the preceding claims

wherein the fields generated by each of the field generators have a different frequency, a different phase, or both a different frequency and a different phase.

8. The locating system of any of the preceding claims, wherein the field generated by each field generator has a different frequency.

9. The locating system of claim 8, wherein the frequencies of the field generators are each integer multiples of a given frequency.

10. The locating system of any of claims 7-9, wherein the signal processor cross-correlates the signals corresponding to the drive and sensor signals.

11. The locating system of claim 9, wherein the signal processor cross-correlates the signals corresponding to the drive and sensor signals and wherein the duration of the cross-correlation of the inputs is the minimal common product of the integer multipliers divided by the given frequency.

12. The locating system of claim 10 or claim 11, wherein the results of the cross-correlation are used to calculate the contribution of each field generator to the signal generated by each said sensor.

13. The locating system of any of the preceding claims wherein the fields are AC magnetic fields.

14. The locating system of claim 13, wherein the AC magnetic fields are continuous fields.

15. The locating system of any of the preceding claims and including a display system for displaying the position of

the point on the invasive medical instrument.

16. The locating system of any of the preceding claims wherein there is an additional sensor on a portion of the invasive medical instrument which senses a local condition.

17. The locating system of claim 16 wherein the additional sensor senses local electrical signals and transfers them to terminals external to the patient's body.

18. The locating system of claim 17, wherein the signals are electrical signals from the endocardium of the patient's heart.

19. The locating system of claim 18, wherein the signal processor processes the position and orientation coordinate signals and the local electrical signals acquired at a plurality of points on the endocardium to generate a map that represents the propagation of electrical signals through tissue in the patient's body.

20. The locating system of any of claims 16-22 wherein the additional sensor is operative for supplying electrical energy to the endocardium for ablating a portion of the endocardium.

21. The locating system of any of claims 1-16 and including an electrode adapted for supplying electrical energy to the endocardium for ablating a portion of the endocardium.

22. The locating system of claim 16 wherein the additional sensor is an ultrasonic transmitter/receiver.

23. The locating system of claim 22 wherein the ultrasonic transmitter/receiver provides a less than three dimensional representation of the acoustic properties of tissue beyond

the distal end.

24. The locating system according to claim 23 wherein the distal end is deflectable.

25. The locating system according to claim 24 and including image reconstruction circuitry which receives a plurality of said less than three dimensional representations acquired at different orientations of the distal end and produces a three dimensional map of the acoustic properties of tissue at least partially surrounding the distal end.

26. The locating system of any of the preceding claims and further comprising a reference instrument which includes a plurality of sensors situated in the reference instrument, wherein said display system displays the position of the point on the invasive medical instrument relative to the position of a point on the reference instrument.

27. The locating system of claim 26, wherein the locating system comprises only a single reference instrument.

28. The locating system of claim 26 or claim 27 wherein the reference instrument is an invasive medical instrument and wherein said sensors are situated proximate the distal end thereof.

29. An imaging system for intra-body ultrasonic imaging comprising:

a invasive medical instrument having an axial-looking ultrasonic imaging transducer attached to a distal end of the instrument, which transducer generates a representation of the acoustic properties of tissue beyond the distal end;

means for manipulating the distal end to change the orientation thereof; and

image reconstruction circuitry which receives a

plurality of said representations acquired at different orientations of the distal end and produces a three dimensional map of the acoustic properties of tissue at least partially surrounding the distal end based on said plurality of representations acquired at different orientations of the distal end.

30. The imaging system of claim 29 and further comprising:

a plurality of field generators which generate known, distinguishable fields in response to drive signals;

a plurality of sensors situated in the invasive medical instrument proximate the distal end thereof which generate sensor signals in response to said fields; and

a signal processor which has an input for a plurality of signals corresponding to said drive signals and said sensor signals and which produces three location coordinates and three orientation coordinates of the a point on the transducer.

31. The imaging system of claim 29 or claim 30 wherein said representations are one or two dimensional representation.

32. The system of any of the preceding claims wherein the invasive medical instrument is a catheter or endoscope.

33. A method of determining the position and orientation of an invasive medical instrument having a distal end, comprising:

(a) generating a plurality of distinguishable, geometrically different AC magnetic fields;

(b) sensing the AC magnetic fields at a plurality of sensors proximate the distal end; and

(c) computing six dimensions of position and orientation of a portion of the invasive medical instrument responsive to signals representative of the generated magnetic fields and the sensed magnetic fields.

34. A method according to claim 33 wherein the plurality of distinguishable, geometrically different fields comprises three such fields.

35. A method according to claim 33 or claim 34 wherein the AC magnetic field is sensed at three points of the invasive medical instrument.

36. A method according to any of claims 33-35 wherein the invasive medical instrument is a catheter or endoscope.

37. An ultrasonic intra-body imaging method comprising:

(a) inserting an ultrasonic transducer into the body, said ultrasonic transducer producing a representation of the acoustic properties of tissue beyond an end of the transducer;

(b) manipulating the orientation of the transducer to provide a plurality of said representations;

(c) determining the six dimensions of position and orientation of the transducer for each of the representations; and

(d) constructing a three dimensional map of the acoustic properties of the tissue in a region at least partially surrounding the end of the transducer from said plurality of representations.

38. A method according to claim 37 wherein:

inserting a transducer comprises inserting an invasive medical instrument into the body of a patient, said ultrasonic transducer being positionally and orientationally fixed with respect to a distal end of the instrument; and

manipulating comprises changing the orientation of the distal end.

39. A method according to claim 37 wherein the

representation is a less than three dimensional representation.

40. A invasive medical instrument comprising a plurality of at least three magnetic field sensors proximate the distal end thereof, said sensors having a fixed orientation therebetween.

41. The instrument of claim 40 wherein each sensor comprises a coil.

42. The instrument of claim 41 wherein said plurality of coils have axes which intersect within a coil.

43. The instrument of any of claims 40-42 wherein the plurality is three.

44. The instrument of claim 41 or claim 42 wherein said plurality of coils comprises three coils and wherein said three coils have axes which do not all intersect in a point.

45. The instrument of any of claims 40-44 and further comprising an ultrasound transducer at said distal end.

46. The instrument of claim 45 wherein said ultrasound transducer provides a representation of the acoustic properties of tissue beyond and along the axis of the catheter.

47. The instrument of claim 46 wherein said representation is a one dimensional representation.

48. The instrument of claim 46 wherein said representation is a two dimensional representation.

49. The instrument of any of claims 40-44 and further

comprising an electrical probe at said distal end.

50. The instrument of claim 49 wherein said electrical probe is adapted to sense electrical signals generated by tissue which is in contact and conduct said signals to the proximal end of the catheter.

51. The instrument of claim 49 or claim 50 wherein said electrical probe is adapted to supply an ablative electrical signal to tissue contacting said probe.

52. The instrument of any of claims 40-44 and including a sensor for measuring local chemistry at the distal end.

53. The instrument of any of claims 40-52 wherein said instrument is a catheter or endoscope.

54. The instrument of any of claims 40-53 and also including means for changing the orientation of the distal end.

55. The instrument of claim 54 wherein the means for changing the orientation comprises;

a relatively more flexible wire passing through the medical instrument that is attached to the distal end and has a bend near the distal end;

a relatively more rigid sleeve which is straight near the distal end and which slideably holds the wire thereat, whereby when the sleeve is slid over the wire, the wire and distal end are straightened.

56. An instrument according to claim 55 wherein instrument has a lengthwise axis and wherein the wire is sited off the axis of the instrument.

57. An instrument according to claim 54 wherein the means

for changing the orientation comprises;

a flat relatively flexible portion being slit along a portion of the length thereof to form two portions which are attached at a first end thereof, said first end being attached to the distal end of the instrument;

a pair of wires, one end of each of which being attached to one of said portions at a second end thereof; and

means for changing the relative lengths of the wires whereby the flexible element is bent, thereby steering the distal end of the instrument.

58. Apparatus for steering the distal end of an invasive medical instrument comprising:

a flat relatively flexible portion being slit along a portion of the length thereof to form two portions which are attached at a first end thereof, said first end being attached to the distal end of the instrument;

a pair of wires, one end of each of which being attached to one of said portions at a second end thereof; and

means for changing the relative lengths of the wires whereby the flexible element is bent, thereby steering the distal end of the instrument.

59. Apparatus according to claim 58 wherein the invasive medical instrument is a catheter or endoscope.

60. A method of producing a three dimensional image of the internal surface of an internal body organ comprising:

measuring the distance to said surface from a plurality of orientations and positions within the internal surface; and

assembling the distance measurements to form an image of the surface.

61. A method according to claim 60 wherein the measurement of distances is preformed utilizing an ultrasonic transducer.

62. A invasive medical instrument comprising a plurality of magnetic field sensors and an ultrasound transducer proximate the distal end thereof.

63. The instrument of claim 62 wherein said ultrasound transducer provides a representation of the acoustic properties of tissue beyond and along the axis of the catheter.

64. The instrument of claim 63 wherein said representation is a one dimensional representation.

65. The instrument of claim 63 wherein said representation is a two dimensional representation.

66. The instrument of any of claims 45-48 and 62-65 wherein the ultrasound transducer is positionally and orientationally fixed with respect to the distal end of the instrument.

67. The instrument of claim 66 and including means for controlably changing the orientation of the transducer by changing the orientation of the distal end of the instrument.

68. The instrument of any of claims 62-67 wherein said instrument is a catheter or endoscope.

FIG. 1

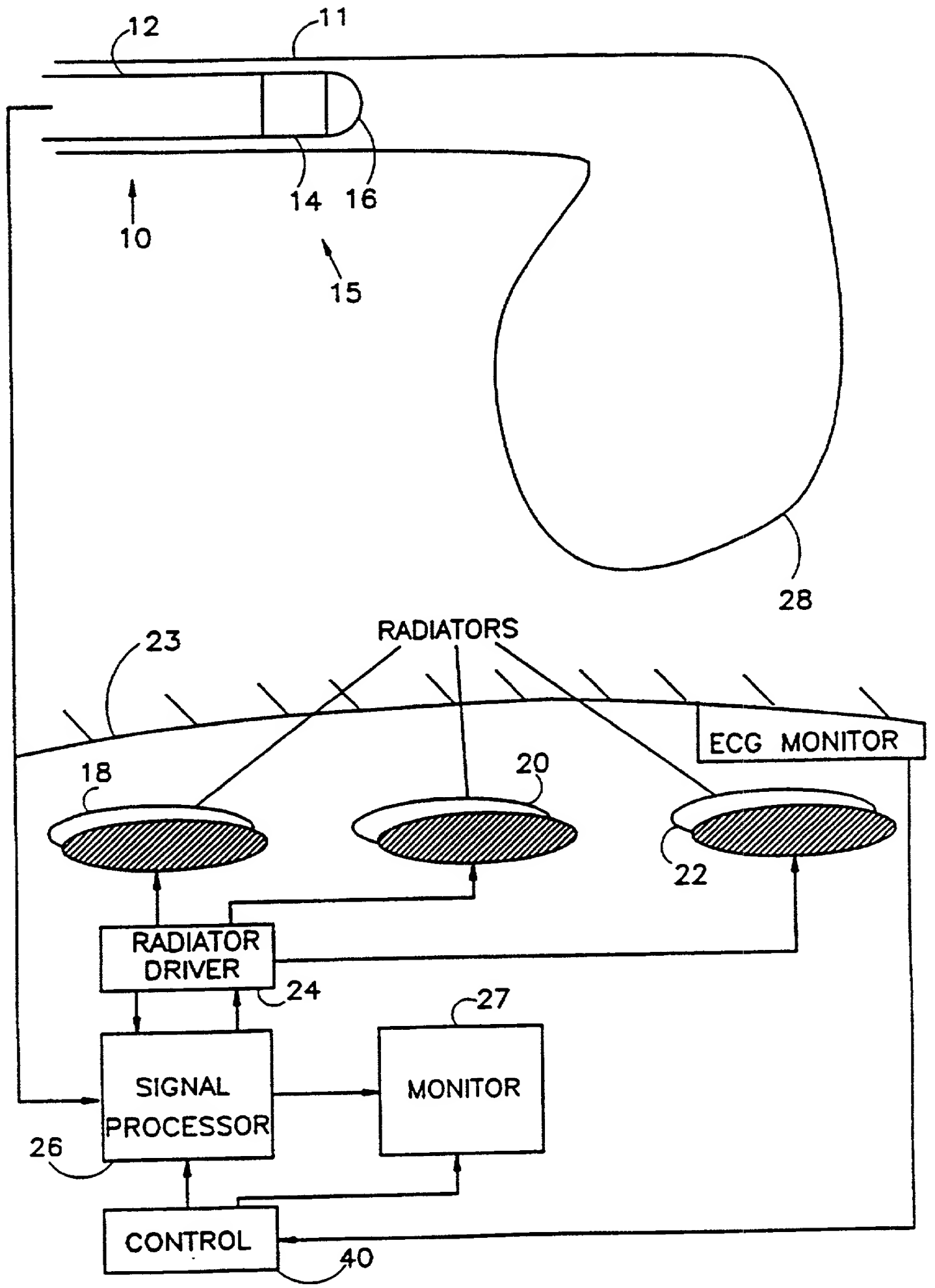
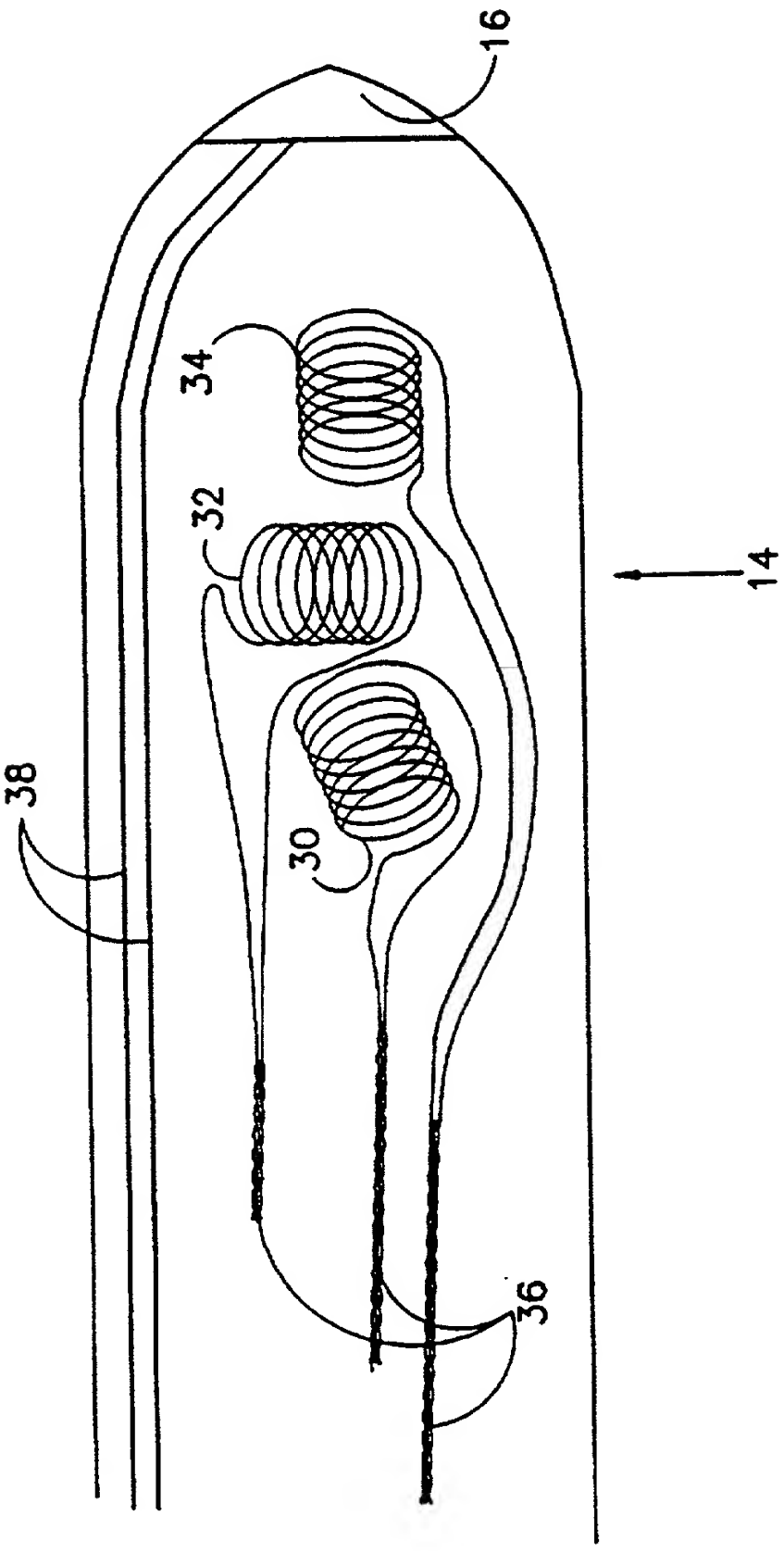

12
11
14
16
10
15
28
RADIATORS
23
ECG MONITOR
18
20
22
RADIATOR DRIVER
24
27
SIGNAL PROCESSOR
MONITOR
26
CONTROL
40

FIG. 2



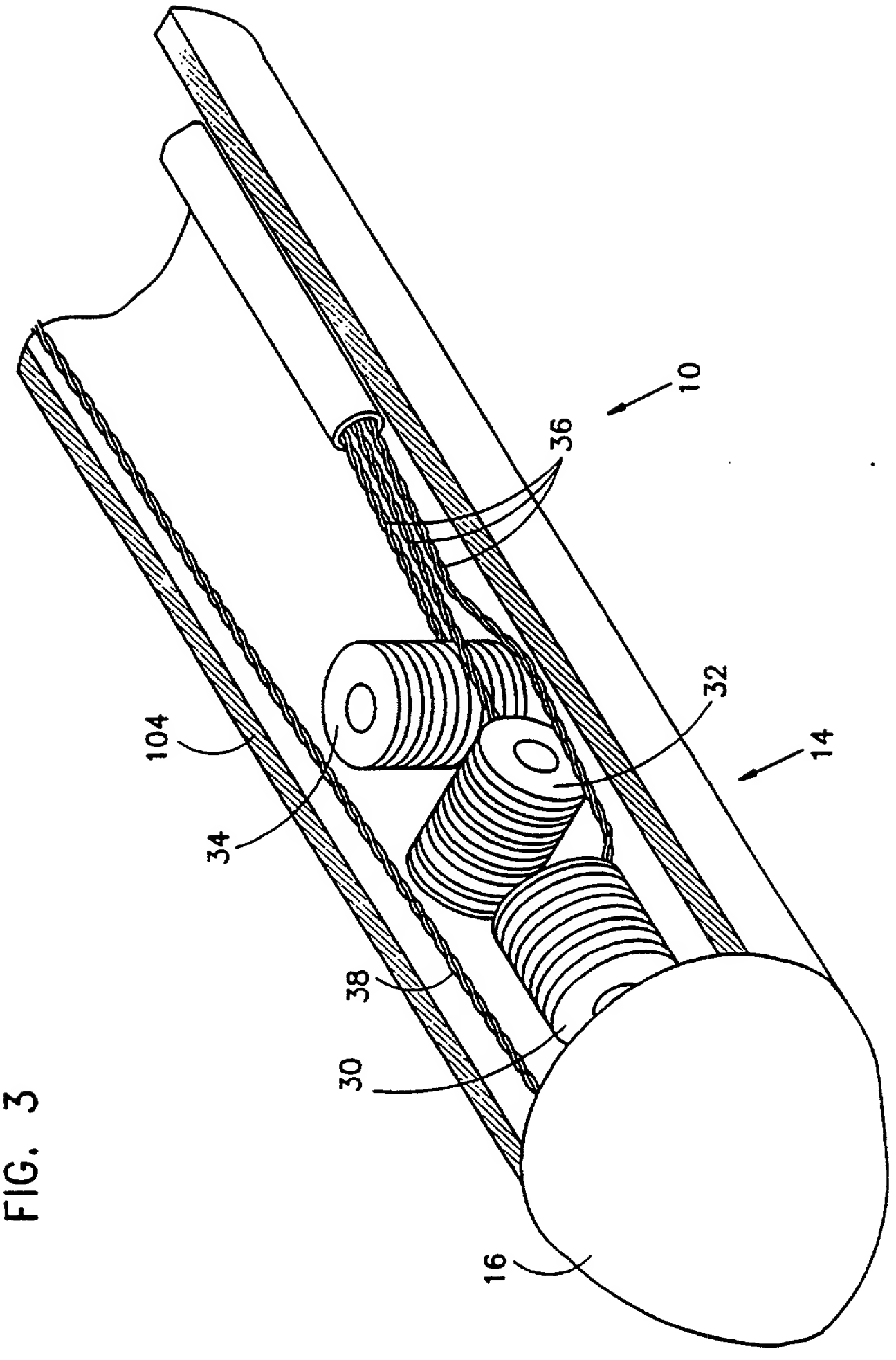


FIG. 3

FIG. 4

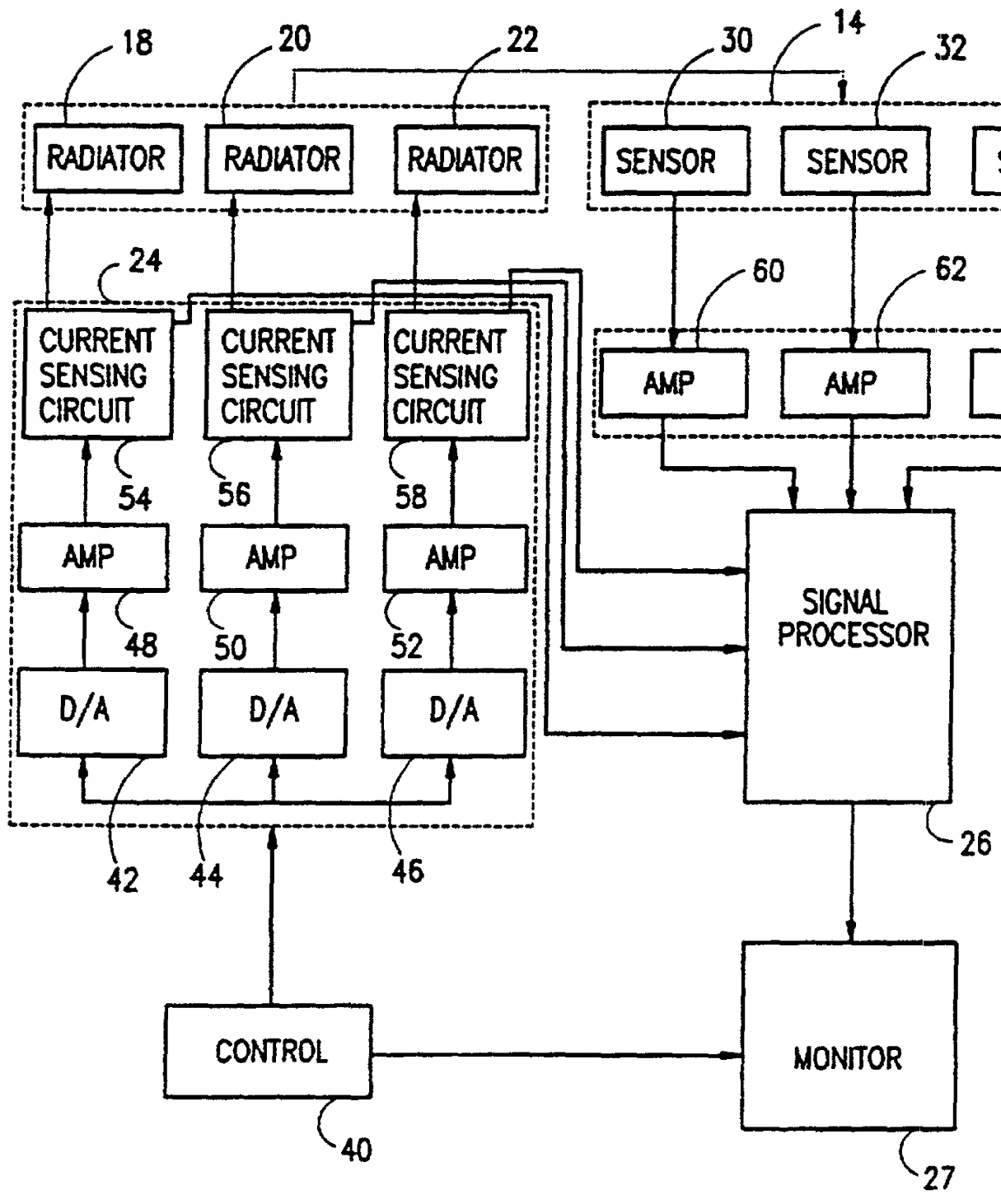

18
20
22
30
14
32
34
RADIATOR
RADIATOR
RADIATOR
SENSOR
SENSOR
SENSOR
24
60
62
64
CURRENT SENSING CIRCUIT
CURRENT SENSING CIRCUIT
CURRENT SENSING CIRCUIT
AMP
AMP
AMP
54
56
58
AMP
AMP
AMP
48
50
52
D/A
D/A
D/A
SIGNAL PROCESSOR
26
42
44
46
CONTROL
MONITOR
40
27

FIG. 5

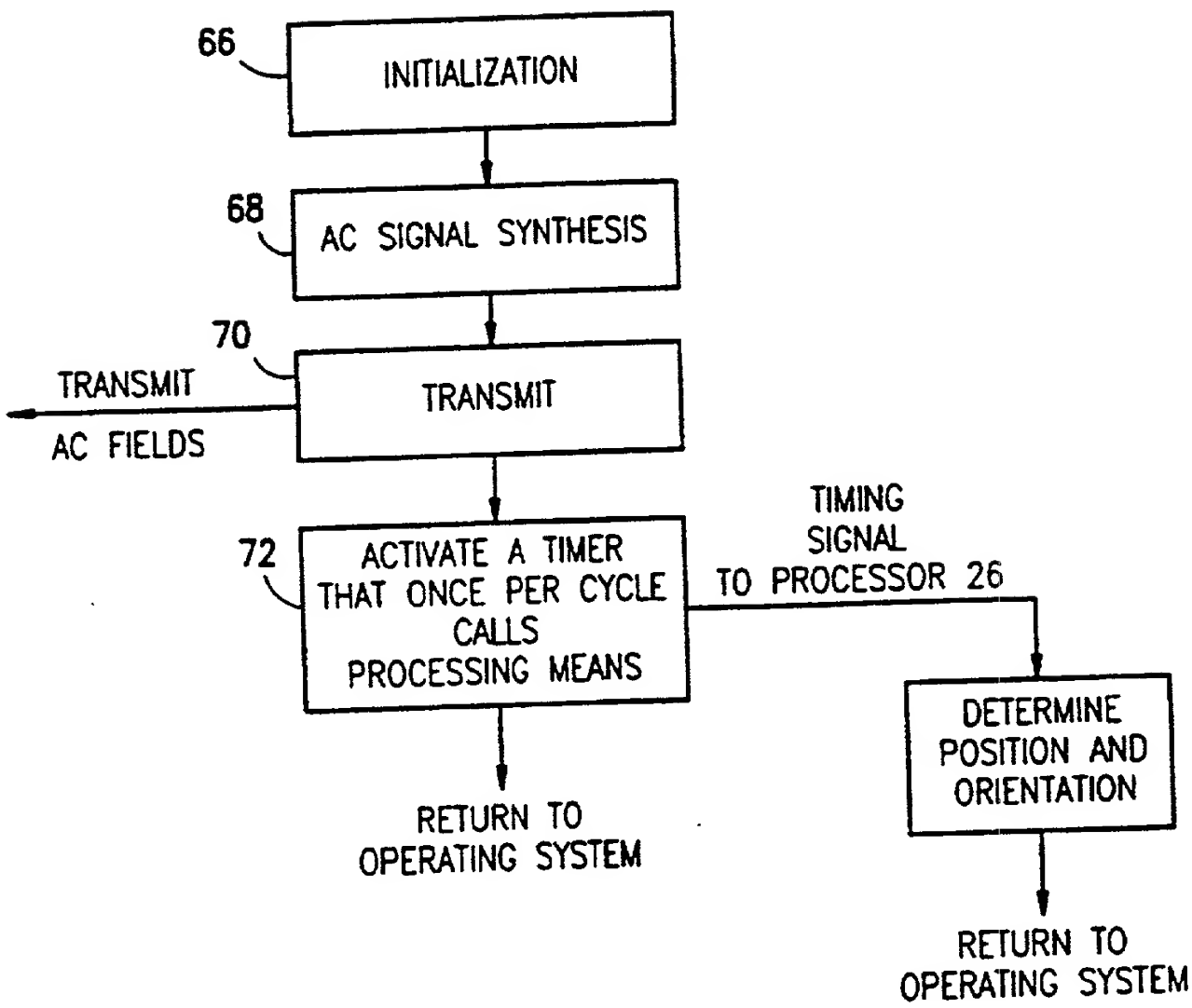

66
INITIALIZATION
68
AC SIGNAL SYNTHESIS
70
TRANSMIT
TRANSMIT
AC FIELDS
72
ACTIVATE A TIMER THAT ONCE PER CYCLE CALLS PROCESSING MEANS
TIMING SIGNAL TO PROCESSOR 26
RETURN TO OPERATING SYSTEM
DETERMINE POSITION AND ORIENTATION
RETURN TO OPERATING SYSTEM

FIG. 6

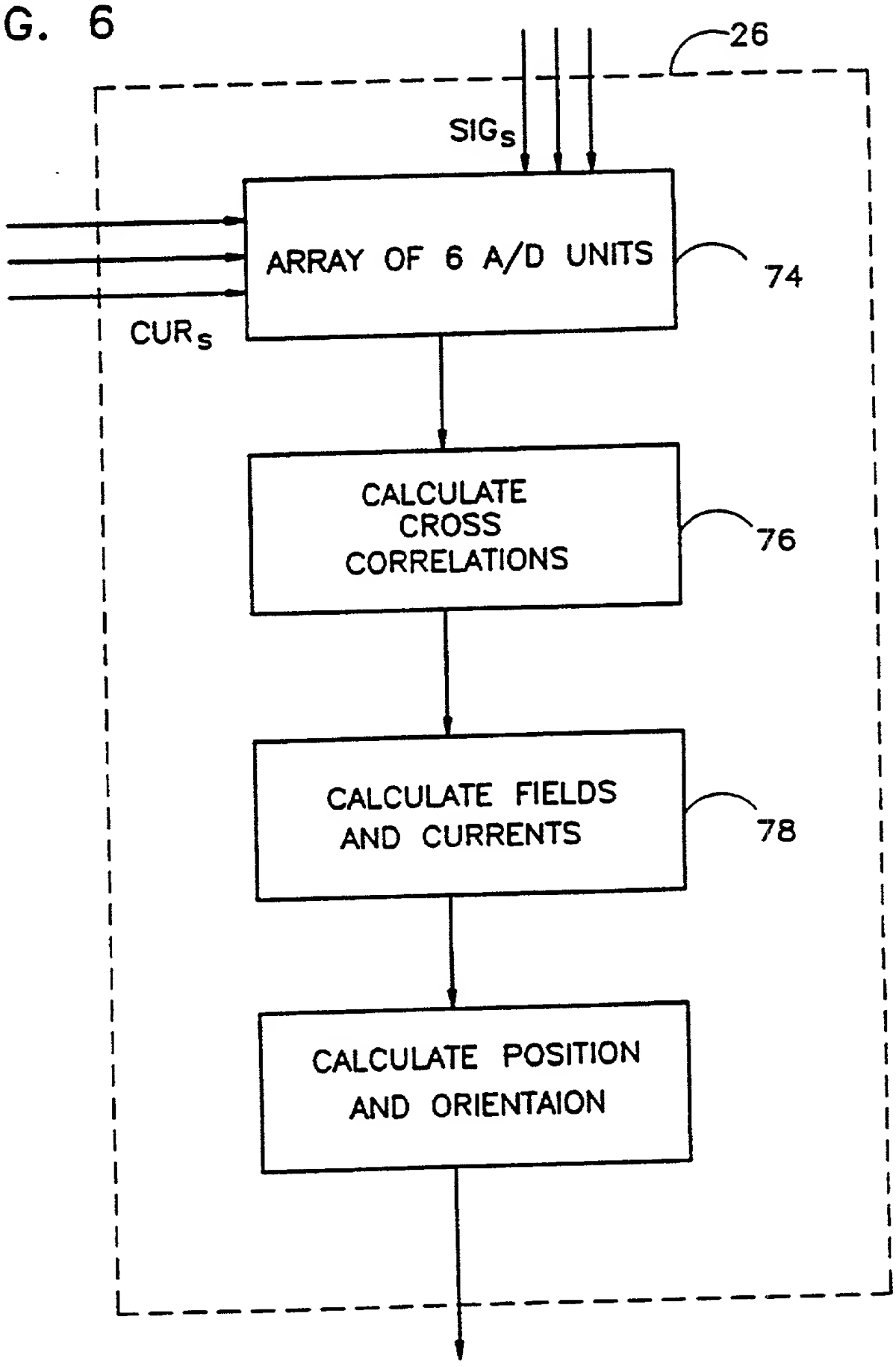

26
SIGs
ARRAY OF 6 A/D UNITS
74
CURs
CALCULATE CROSS CORRELATIONS
76
CALCULATE FIELDS AND CURRENTS
78
CALCULATE POSITION AND ORIENTAION

FIG. 7

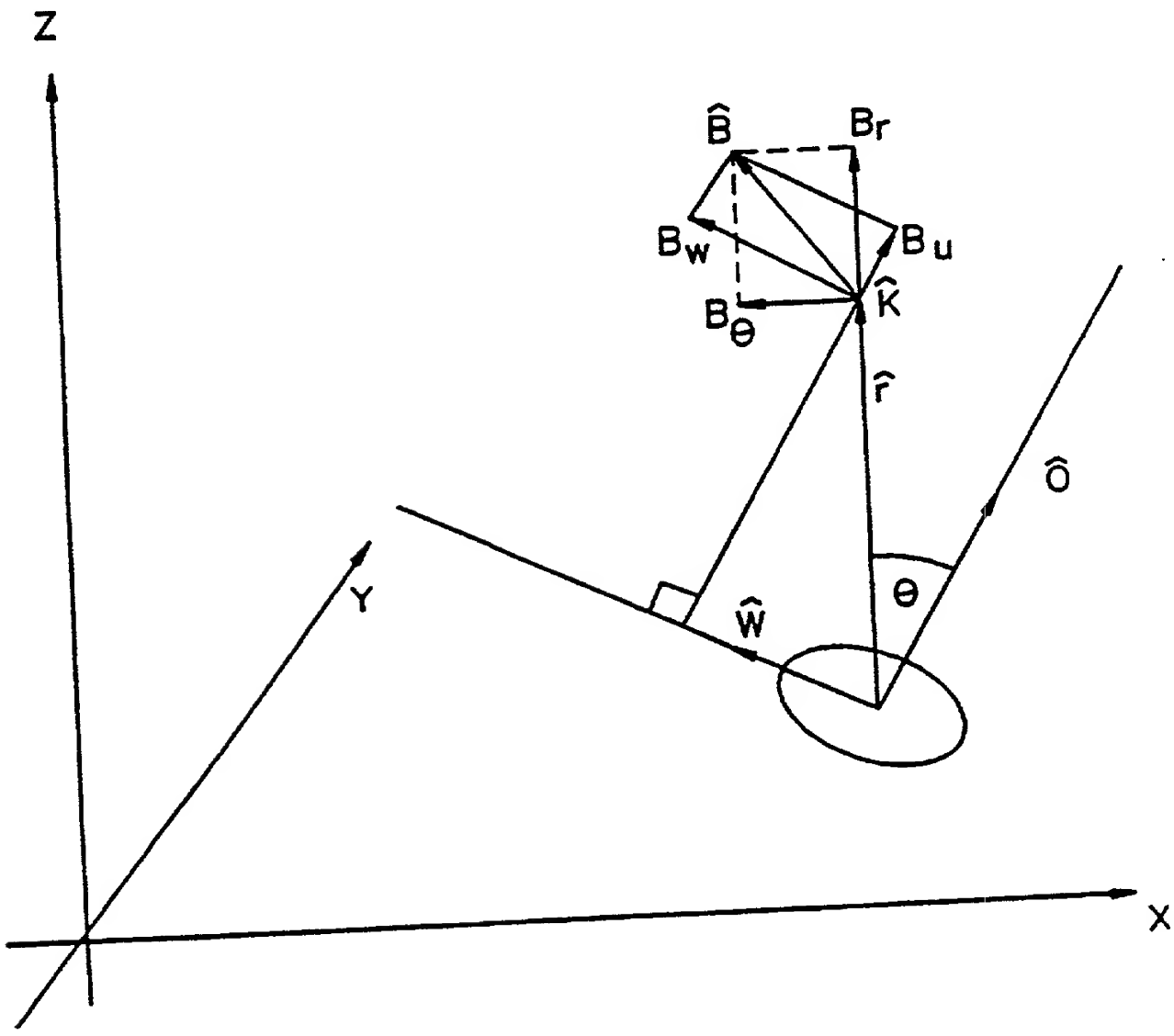


FIG. 8

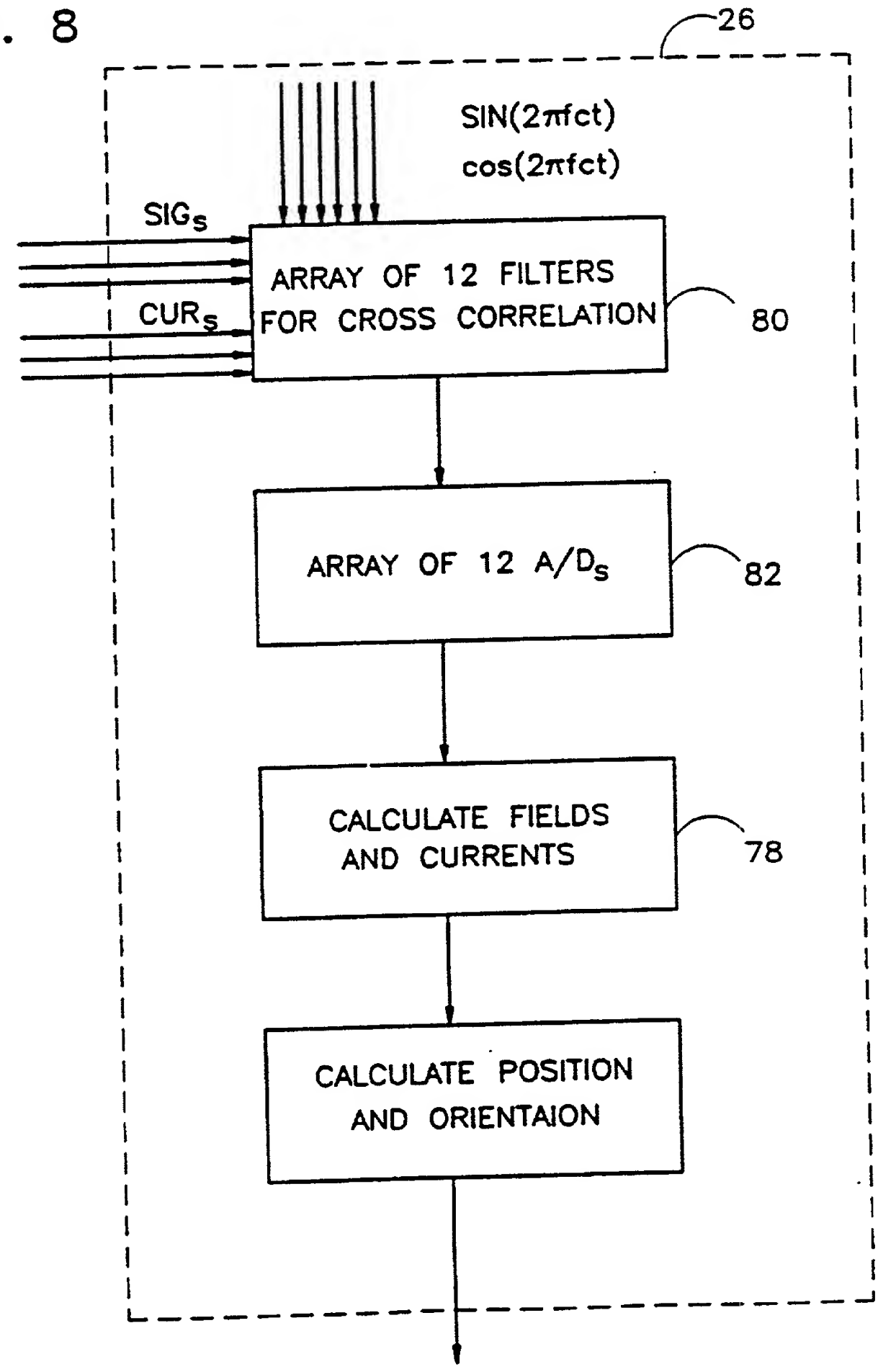
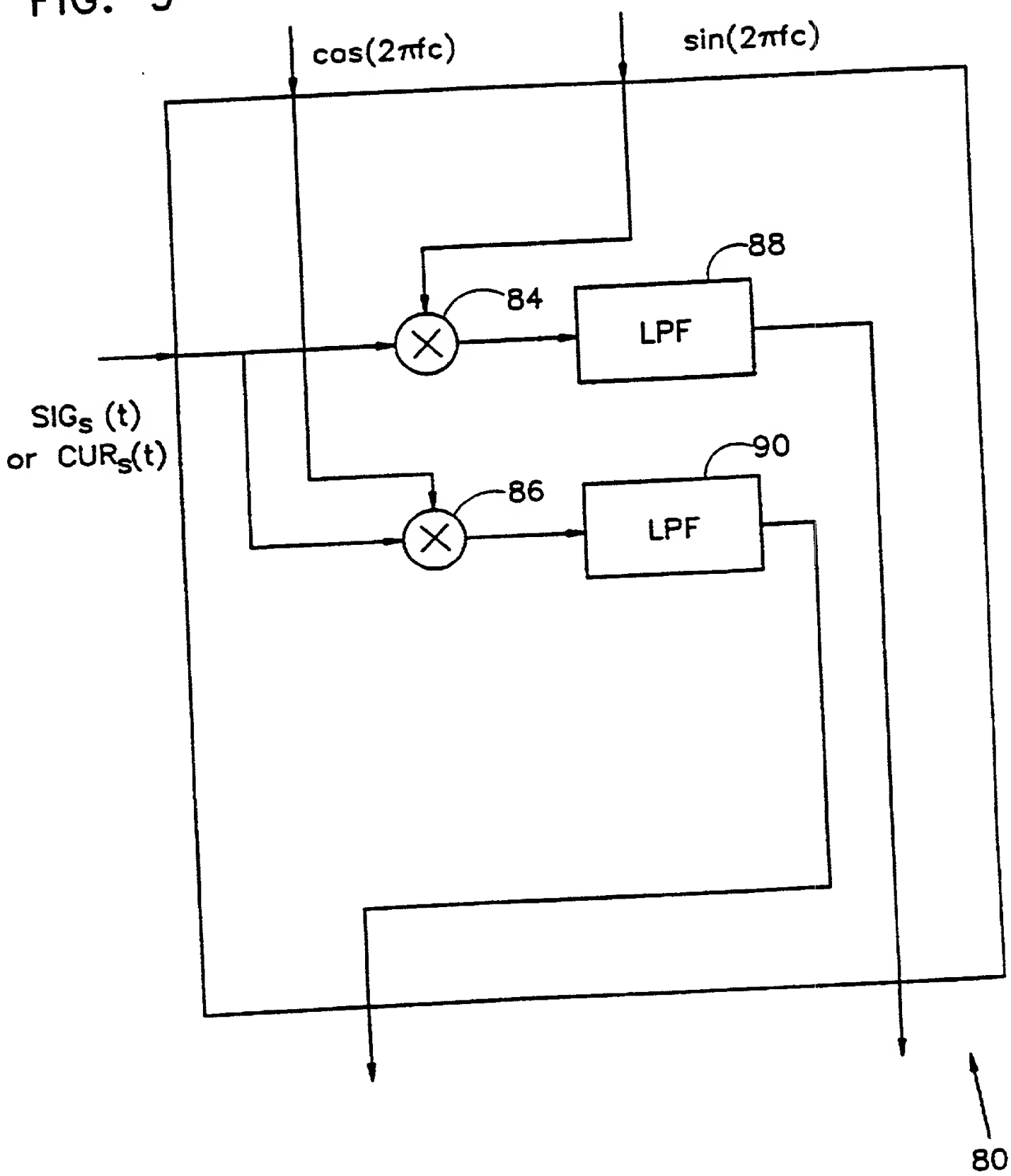


FIG. 9



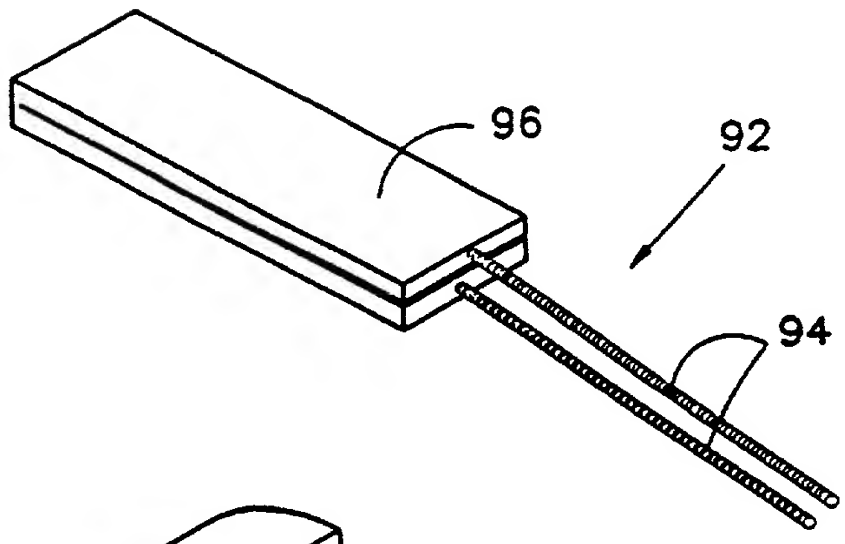


FIG. 10A

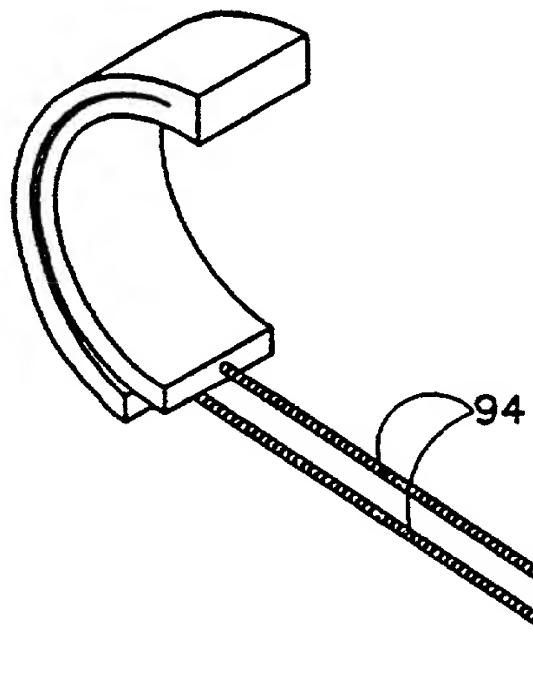


FIG. 10B

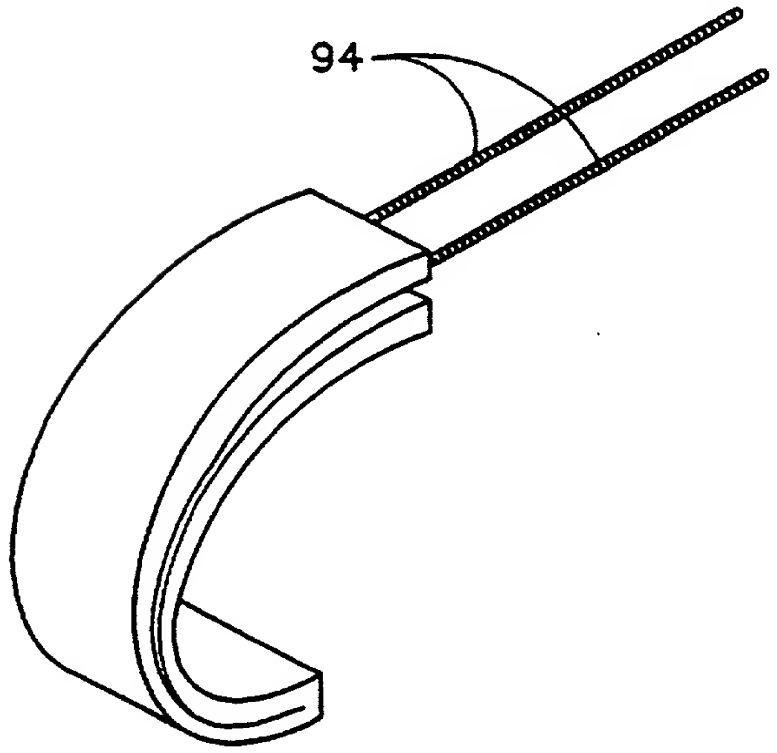


FIG. 10C

FIG. 10D

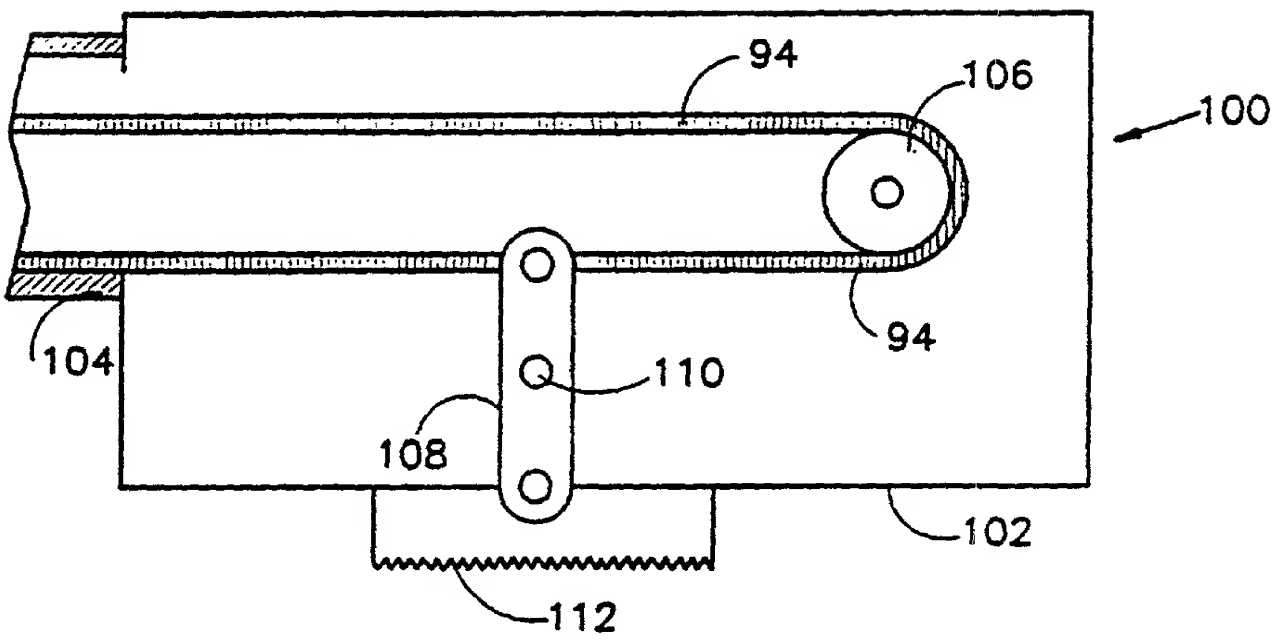


FIG. 11

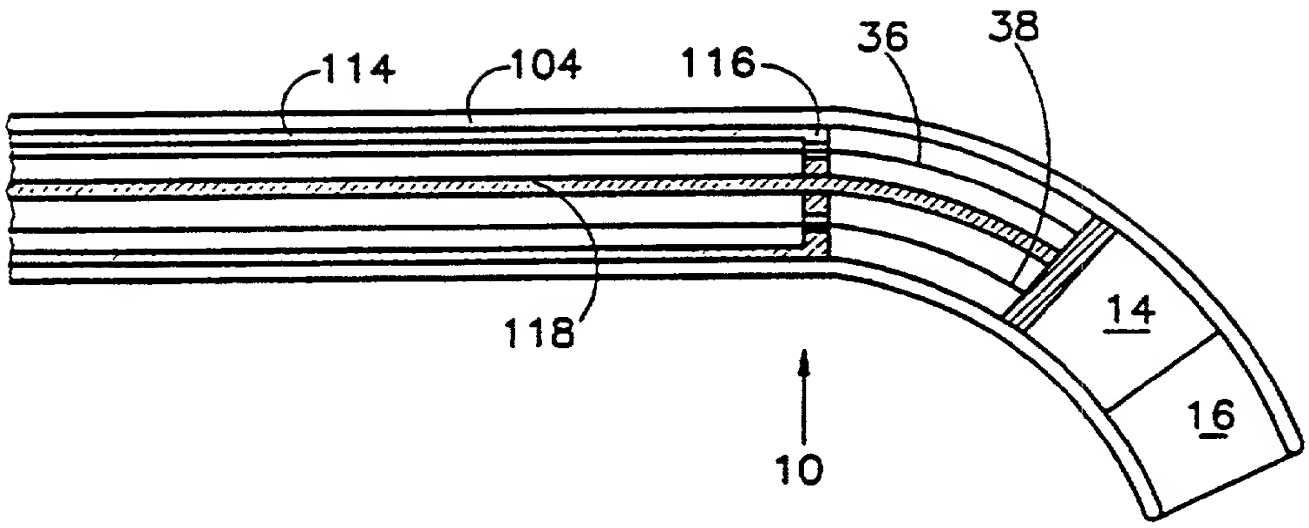


FIG. 12

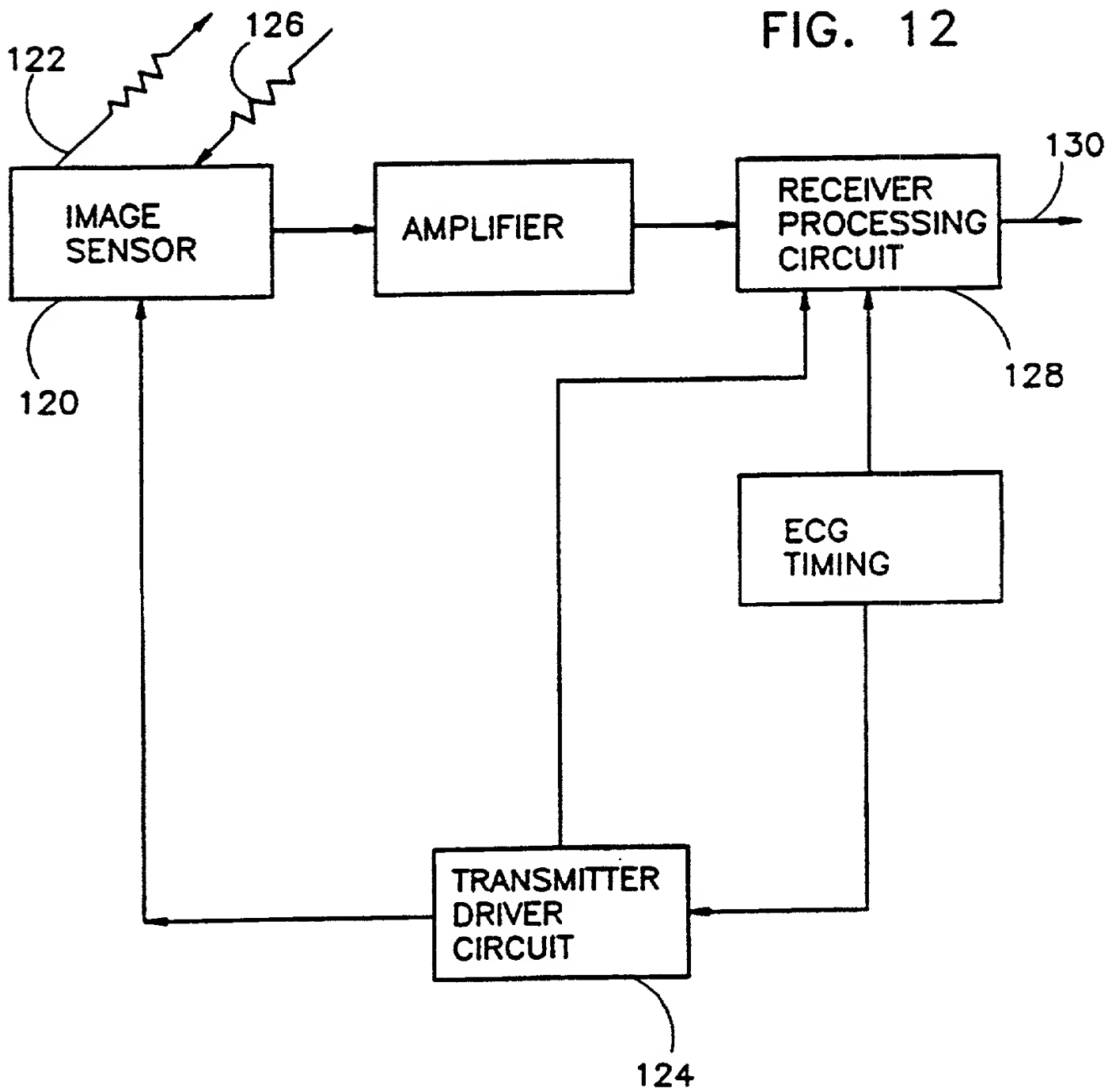
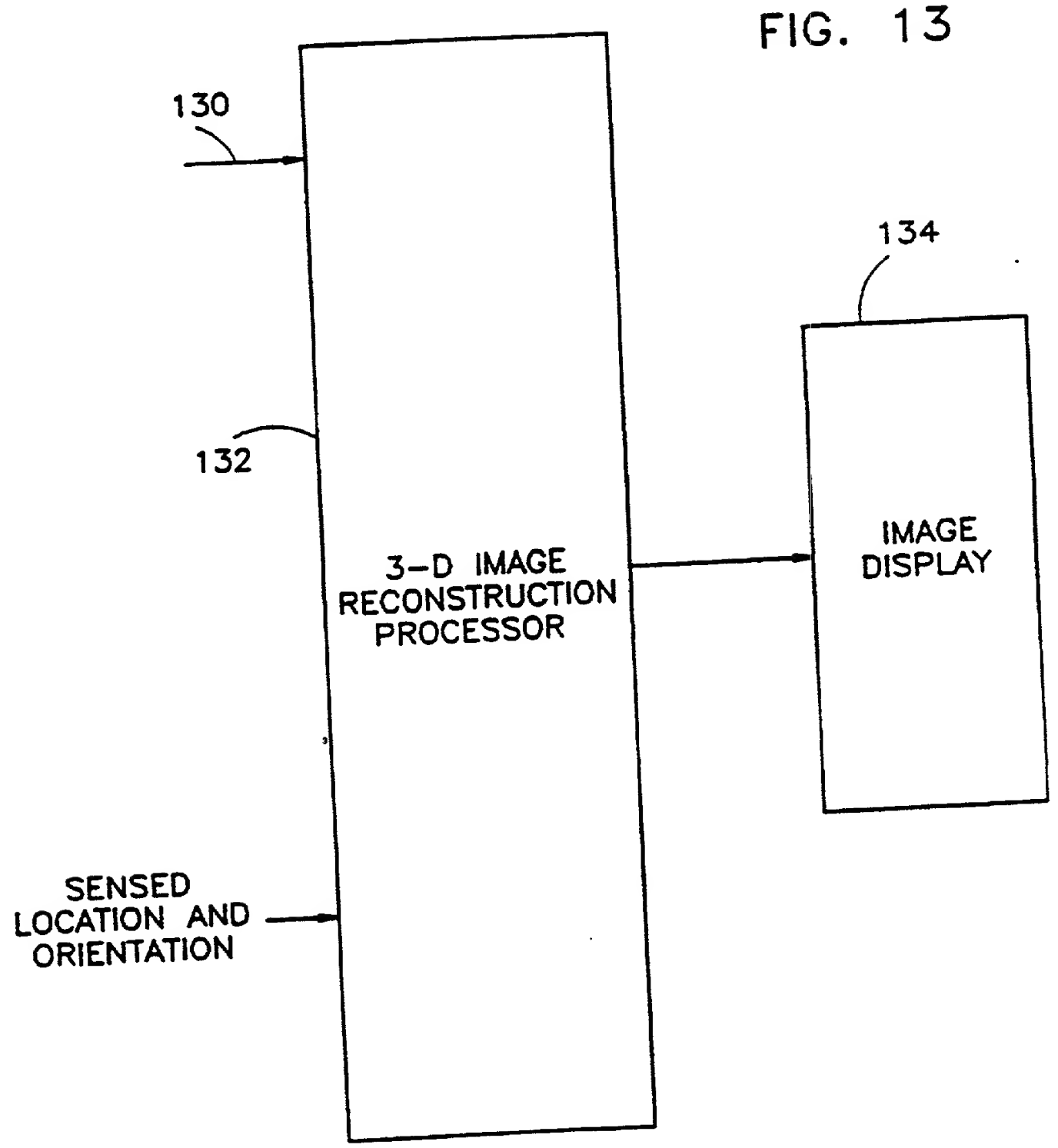


FIG. 13



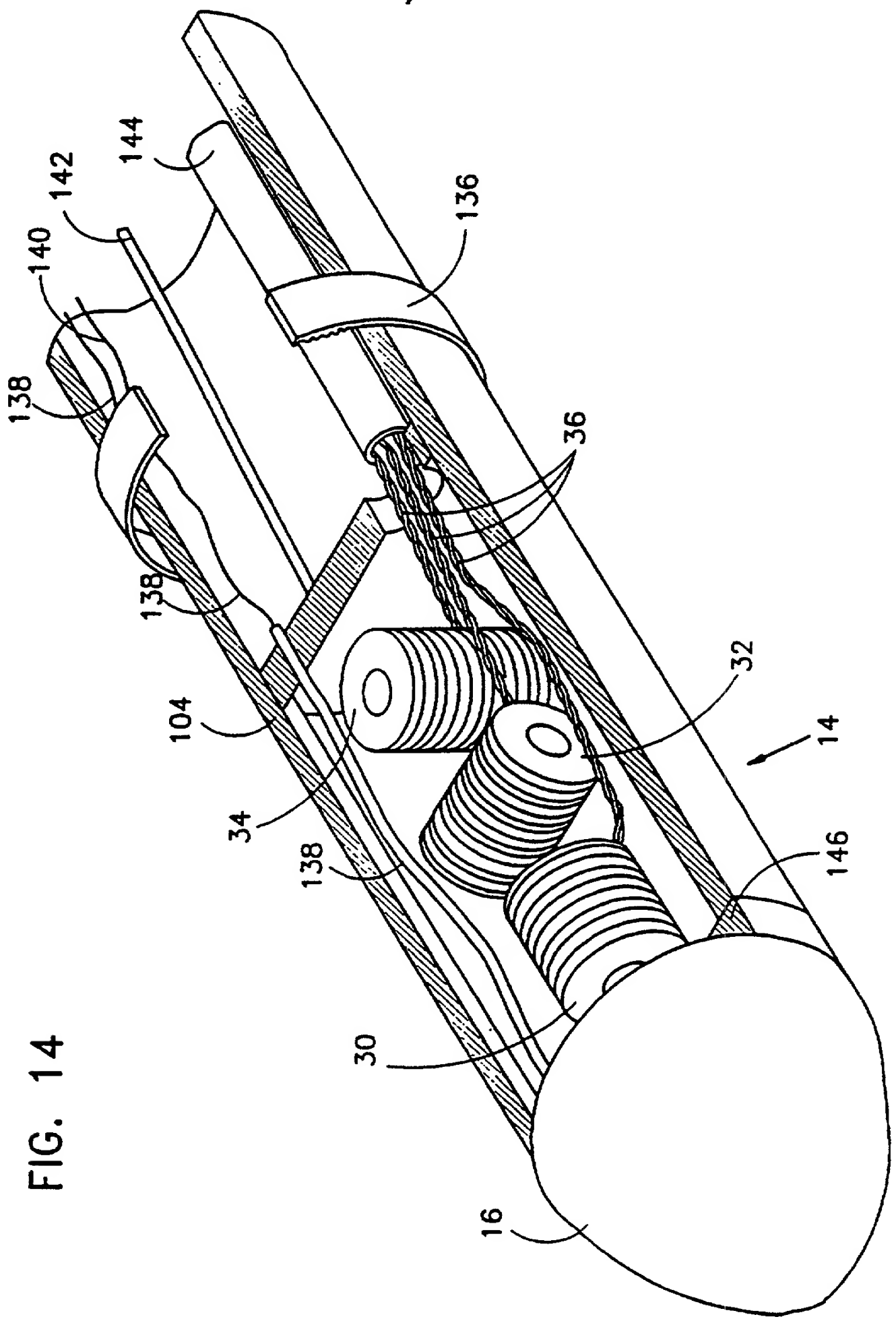


FIG. 14

FIG. 15

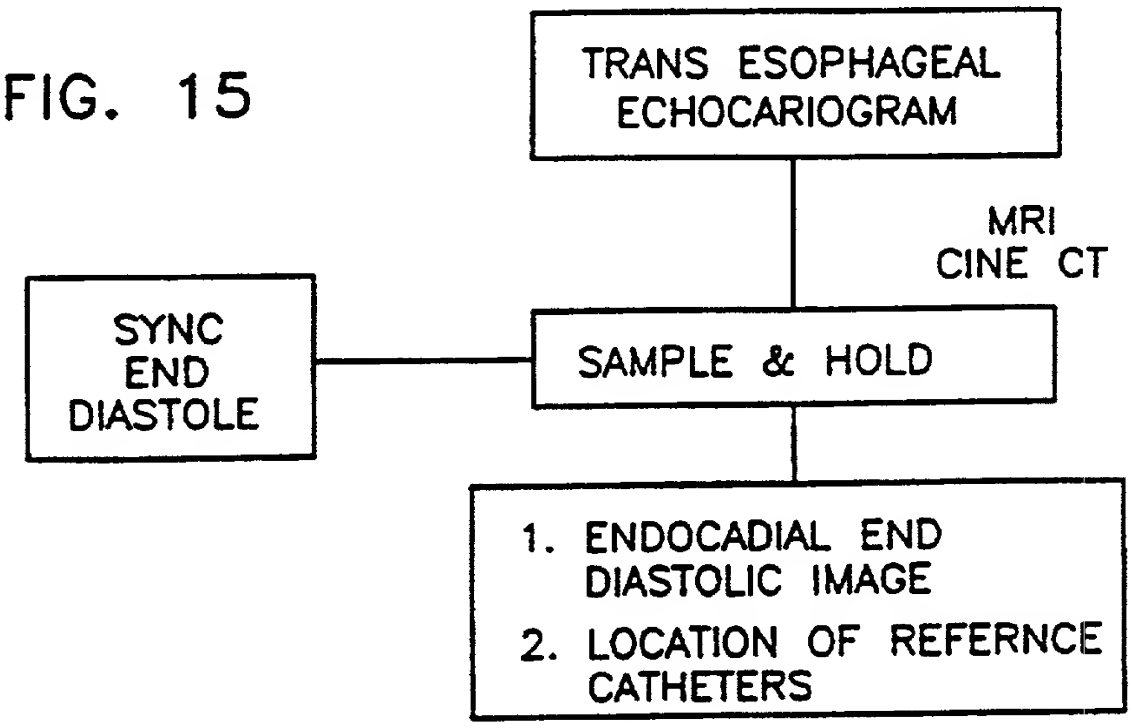

TRANS ESOPHAGEAL ECHOCARIOGRAM
MRI
CINE CT
SYNC
END
DIASTOLE
SAMPLE & HOLD
1. ENDOCADIAL END DIASTOLIC IMAGE
2. LOCATION OF REFERNCE CATHETERS

FIG. 19

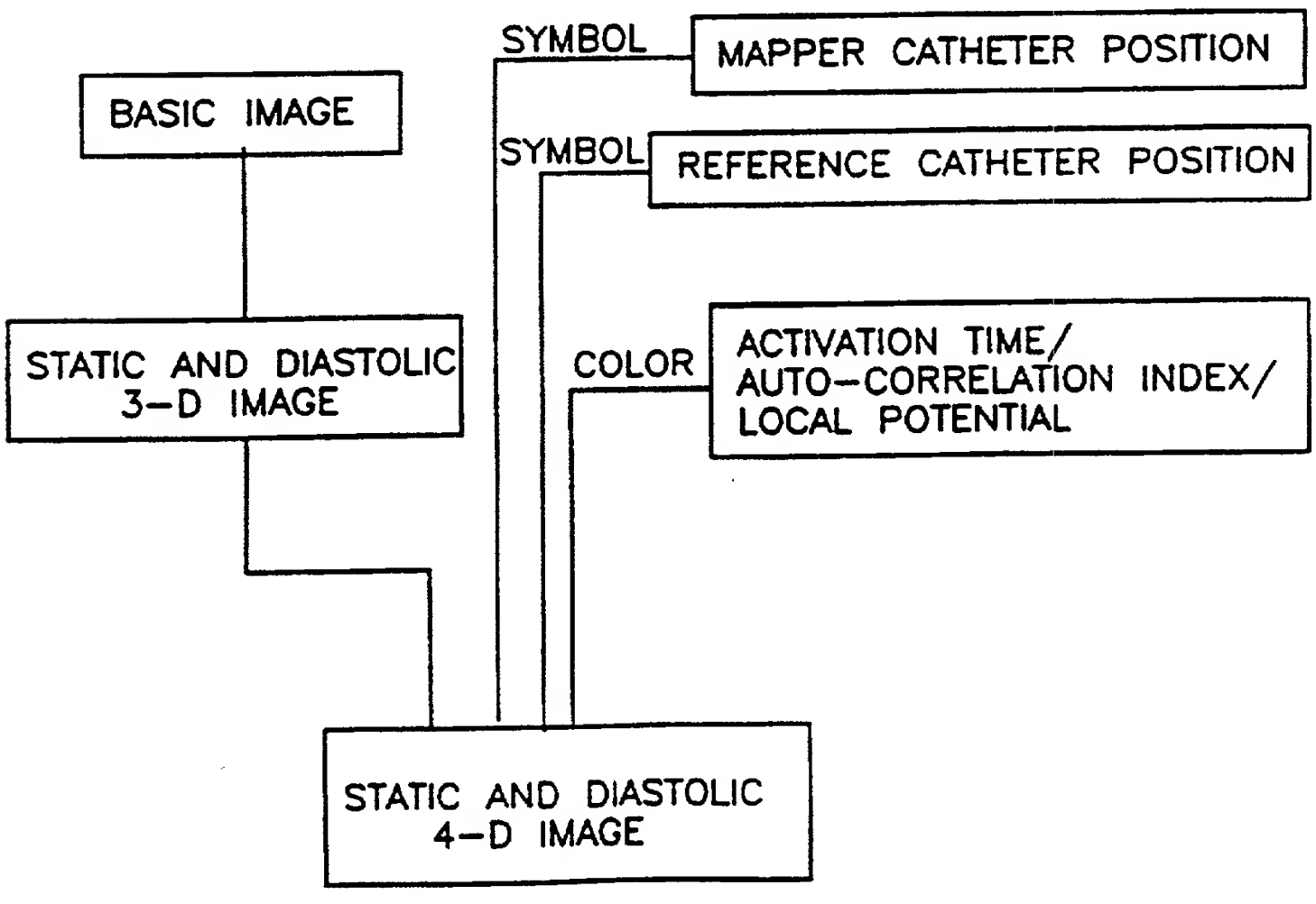

SYMBOL
MAPPER CATHETER POSITION
BASIC IMAGE
SYMBOL
REFERENCE CATHETER POSITION
STATIC AND DIASTOLIC 3-D IMAGE
COLOR
ACTIVATION TIME/
AUTO-CORRELATION INDEX/
LOCAL POTENTIAL
STATIC AND DIASTOLIC 4-D IMAGE

FIG. 16

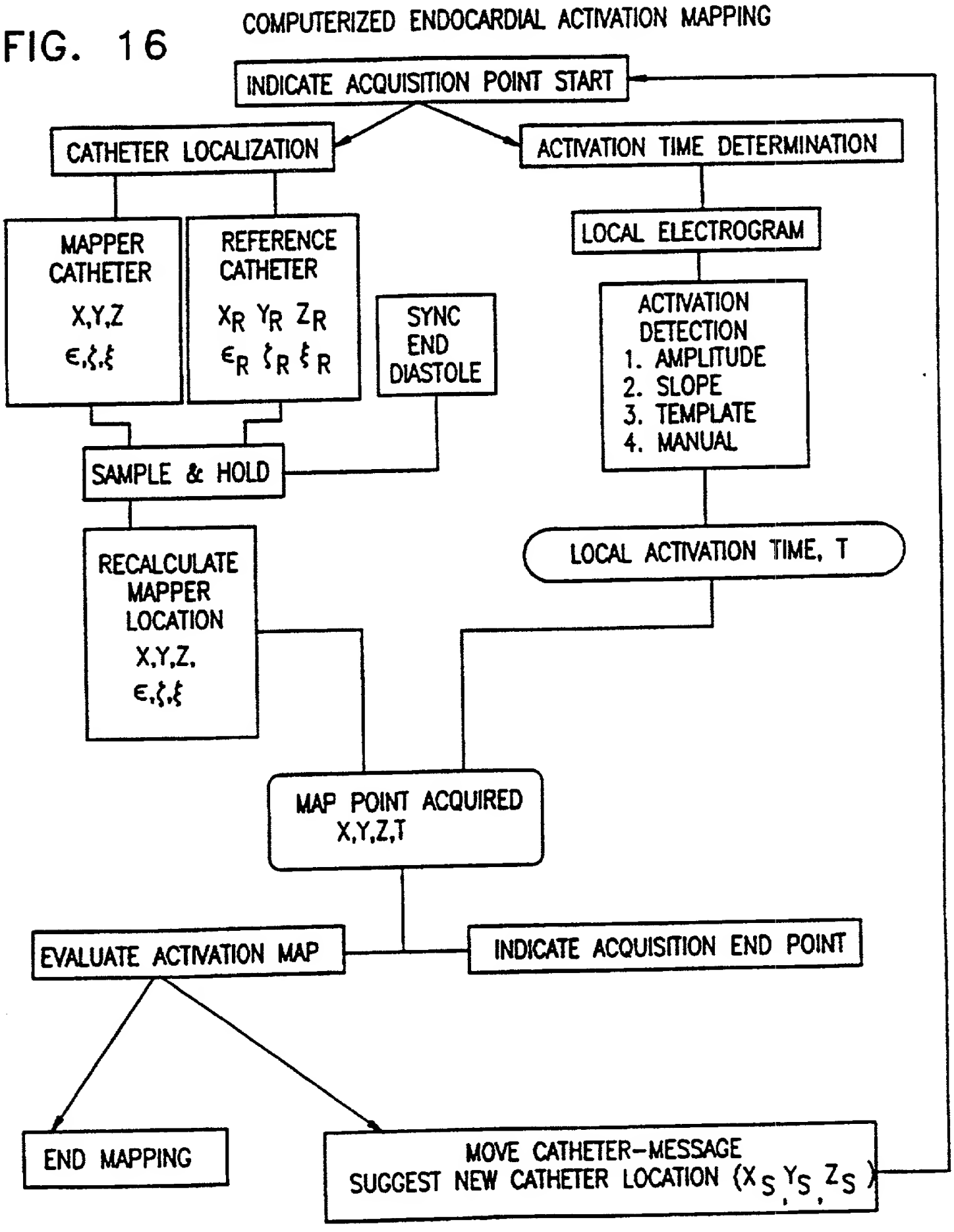
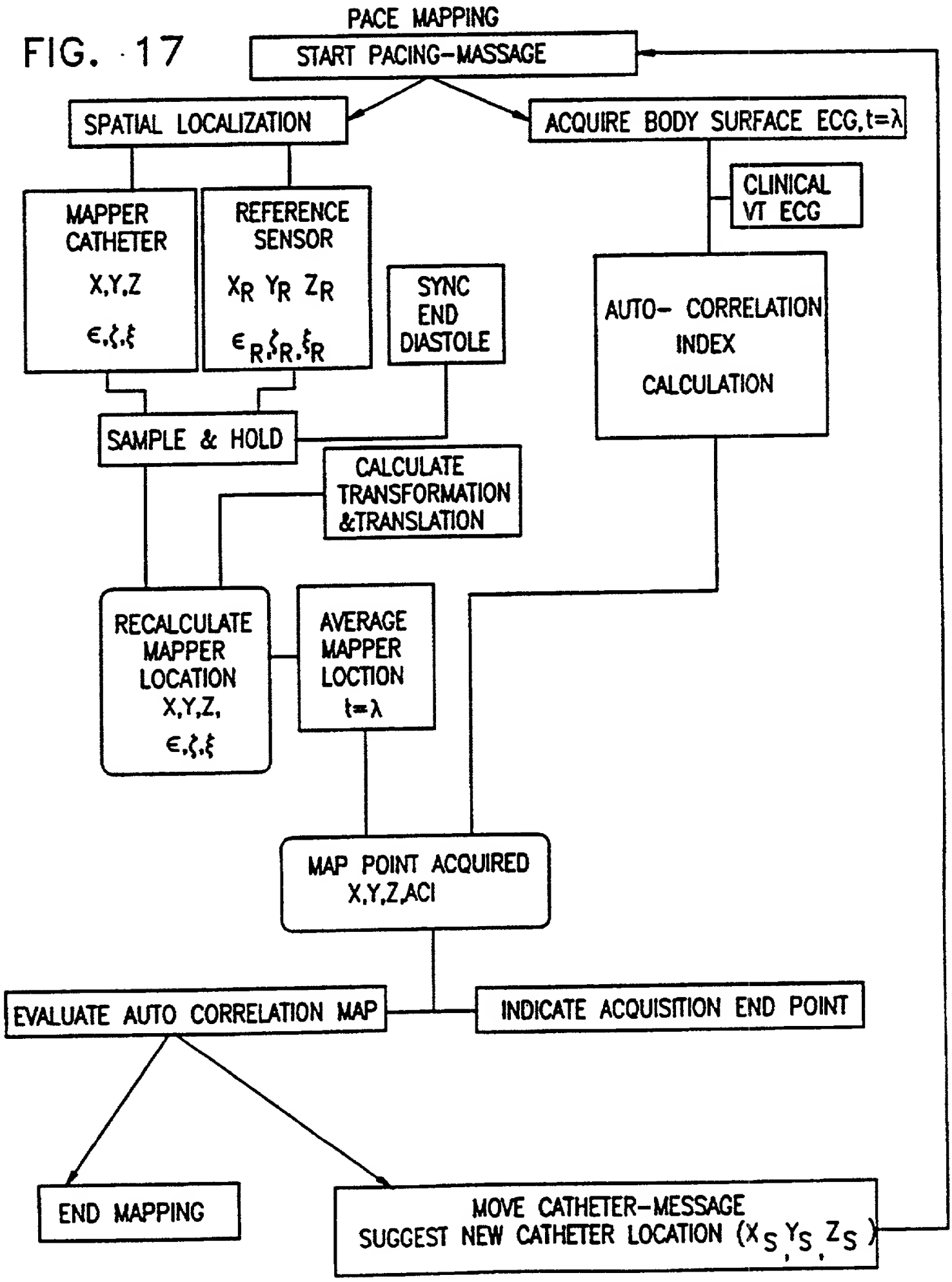

COMPUTERIZED ENDOCARDIAL ACTIVATION MAPPING
INDICATE ACQUISITION POINT START
CATHETER LOCALIZATION
ACTIVATION TIME DETERMINATION
MAPPER CATHETER
X,Y,Z
∈,ξ,ξ
REFERENCE CATHETER
X_R Y_R Z_R
ϵ_R ζ_R ξ_R
SYNC END DIASTOLE
LOCAL ELECTROGRAM
ACTIVATION DETECTION
1. AMPLITUDE
2. SLOPE
3. TEMPLATE
4. MANUAL
SAMPLE & HOLD
RECALCULATE MAPPER LOCATION
X,Y,Z,
∈,ξ,ξ
LOCAL ACTIVATION TIME, T
MAP POINT ACQUIRED
X,Y,Z,T
EVALUATE ACTIVATION MAP
INDICATE ACQUISITION END POINT
END MAPPING
MOVE CATHETER-MESSAGE
SUGGEST NEW CATHETER LOCATION (X_S, Y_S, Z_S)

FIG. 17



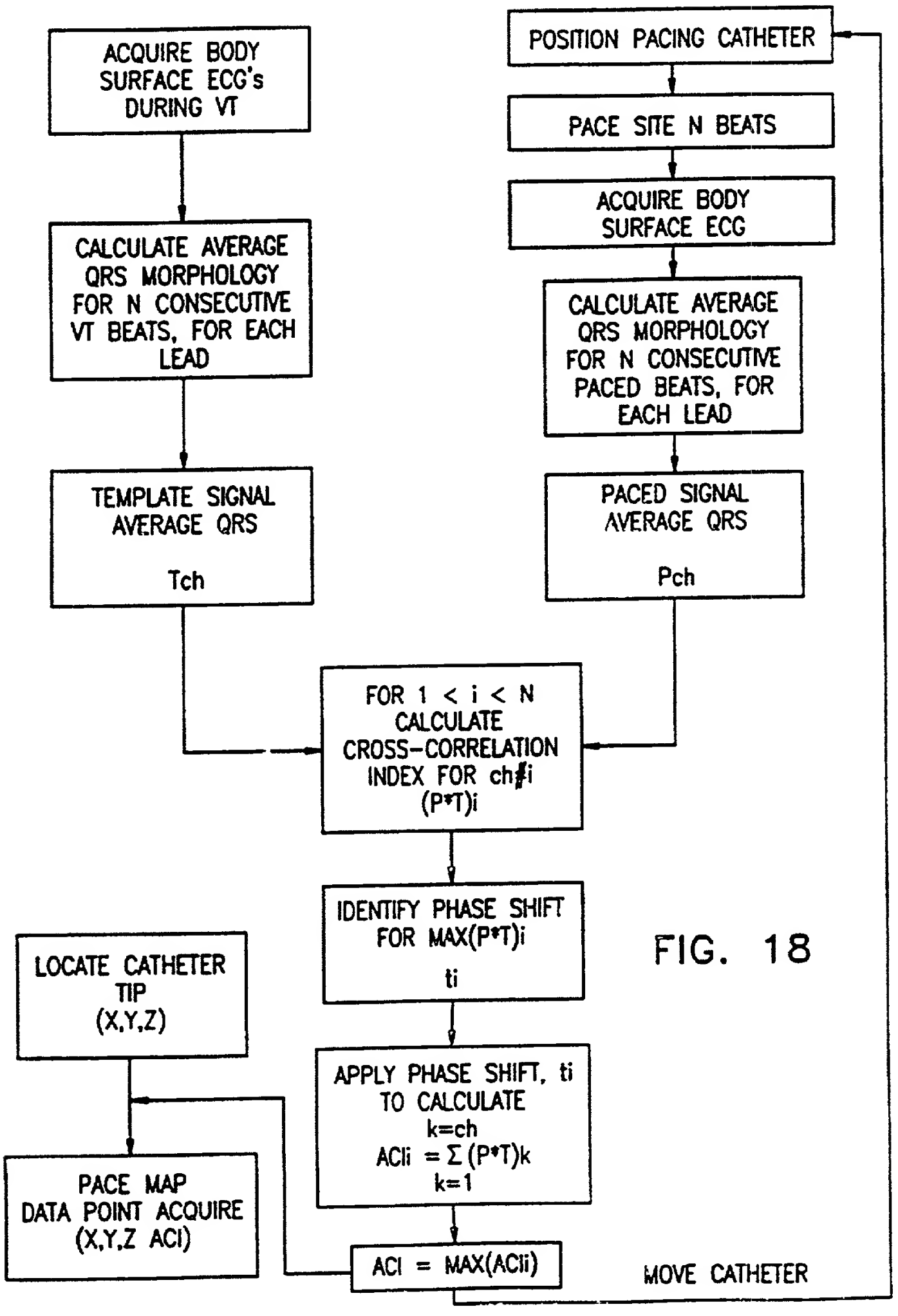

ACQUIRE BODY SURFACE ECG's DURING VT
CALCULATE AVERAGE QRS MORPHOLOGY FOR N CONSECUTIVE VT BEATS, FOR EACH LEAD
TEMPLATE SIGNAL AVERAGE QRS
Tch
POSITION PACING CATHETER
PACE SITE N BEATS
ACQUIRE BODY SURFACE ECG
CALCULATE AVERAGE QRS MORPHOLOGY FOR N CONSECUTIVE PACED BEATS, FOR EACH LEAD
PACED SIGNAL AVERAGE QRS
Pch
FOR 1 < i < N CALCULATE CROSS-CORRELATION INDEX FOR ch#i (P*T)i
IDENTIFY PHASE SHIFT FOR MAX(P*T)i
ti
LOCATE CATHETER TIP (X,Y,Z)
APPLY PHASE SHIFT, ti TO CALCULATE k=ch ACIi = Σ (P*T)k k=1
PACE MAP DATA POINT ACQUIRE (X,Y,Z ACI)
ACI = MAX(ACIi)
MOVE CATHETER

FIG. 18

DECLARATION AND POWER OF ATTORNEY - ORIGINAL APPLICATION	Attorney's Docket No. 20140-85

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

the specification of which

(check one) ☐ is attached hereto.

☒ was filed on February 19, 1997

as Application Serial No. 08/793,371

and was amended on February 19, 1997

(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED
			☐ Yes ☐ No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below

APPLICATION NUMBER	FILING DATE

PRIOR U.S. APPLICATION(S)

APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)
PCT/US95/01103	24.01.95	Pending
08/293,859	19.08.94	Abandoned

POWER OF ATTORNEY

As a named inventor, I hereby appoint Michael I. Wolfson, Registration No. 24,750; William H. Dippert, Registration No. 26,723; R. Lewis Gable, Registration No. 22,479; Morey B. Wildes, Registration No. 36,968; and Regan L. Trumper, Registration No. 38,345 to prosecute this application and to transact all business in the United States Patent and Trademark Office in connection therewith.

SEND CORRESPONDENCE TO: William H. Dippert COWAN, LIEBOWITZ & LATMAN, P.C. 1133 Avenue of the Americas New York, New York 10036-6799			**Direct telephone calls to:** William H. Dippert (212) 790-9200	
201	**Full Name of Inventor**	**Family Name** BEN-HAIM	**First Given Name** Shlomo	**Second Given Name**
	Residence & Citizenship	**City** Haifa	**State or Foreign Country** Israel	**Country of Citizenship** Israel
	Post Office Address	101 Yafe Nof Street, Haifa 34454, Israel		
202	**Full Name of Inventor**	**Family Name** OSADCHY	**First Given Name** Daniel	**Second Given Name**
	Residence & Citizenship	**City** Haifa	**State or Foreign Country** Israel	**Country of Citizenship** Israel
	Post Office Address	48A Harofe Street, Haifa 34367, Israel		
203	**Full Name of Inventor**	**Family Name** PELESS	**First Given Name** Udi	**Second Given Name**
	Residence & Citizenship	**City** Even-Yehuda	**State or Foreign Country** Israel	**Country of Citizenship** Israel
	Post Office Address	P.O.B. 420, Even-Yehuda 45000, Israel		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR - 201	SIGNATURE OF INVENTOR - 202	SIGNATURE OF INVENTOR - 203
Date 5/1/97	Date 5/5/97	Date

WHD/BBB/20140/85/236826.01

POWER OF ATTORNEY

As a named inventor, I hereby appoint Michael I. Wolfson, Registration No. 24,750; William H. Dippert, Registration No. 26,723; R. Lewis Gable, Registration No. 22,479; Morey B. Wildes, Registration No. 36,968; and Regan L. Trumper, Registration No. 38,345 to prosecute this application and to transact all business in the United States Patent and Trademark Office in connection therewith.

SEND CORRESPONDENCE TO:
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201	Full Name of Inventor	Family Name BEN-HAIM	First Given Name Shlomo	Second Given Name
	Residence & Citizenship	City Haifa	State or Foreign Country Israel	Country of Citizenship Israel
	Post Office Address	101 Yafe Nof Street, Haifa 34454, Israel		
202	Full Name of Inventor	Family Name OSADCHY	First Given Name Daniel	Second Given Name
	Residence & Citizenship	City Haifa	State or Foreign Country Israel	Country of Citizenship Israel
	Post Office Address	48A Herofe Street, Haifa 34367, Israel		
203	Full Name of Inventor	Family Name PELESS	First Given Name Udi	Second Given Name
	Residence & Citizenship	City Even-Yehuda	State or Foreign Country Israel	Country of Citizenship Israel
	Post Office Address	P.O.B. 420, Even-Yehuda 45000, Israel		

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR - 201	SIGNATURE OF INVENTOR - 202	SIGNATURE OF INVENTOR - 203
Date 5/1/97	Date	Date 4/5/97

ADDITIONAL INVENTOR(S)

204	Full Name of Inventor	Family Name GREENBERG	First Given Name Ilan	Second Given Name
	Residence & Citizenship	City Haifa	State or Foreign Country Israel	Country of Citizenship Israel
	Post Office Address	15 Geula Street, Haifa 33198, Israel		
205	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address			
206	Full Name of Inventor	Family Name	First Given Name	Second Given Name
	Residence & Citizenship	City	State or Foreign Country	Country of Citizenship
	Post Office Address			

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR - 204	SIGNATURE OF INVENTOR - 205	SIGNATURE OF INVENTOR - 206
Date 5.1.97	Date	Date